

US3292312 (Prod: Clinical Trials of Texas, Inc)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:30:59

All time stamps listed in this document are displayed in GMT

US3292312

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 14:10:33

Generated On: 09 Jun 2021 16:30:59

[Participant ID](#)

US3292312

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

US3292312

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 25 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 |

US3292312

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Apr 2021 14:40:36

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1963 |
| Age | 56 |
| Age Units | YEARS |
| Age (Derived) | 56 |
| Sex | Female <input type="radio"/> Male <input checked="" type="radio"/> |
| Ethnicity | Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/> |
| Race (Check All That Apply) | |
| White | True |
| Black | False |
| Asian | False |
| American Indian or Alaska Native | False |
| Native Hawaiian or other Pacific Islander | False |
| Other | False |
| If race is Other, specify _____ | |
| Unknown | False |
| Not reported | False |

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 25 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 type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, indicate reason for screen fail | Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/> |
| If reason for screen fail is Other, specify | |
| Was this participant screened previously? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If Yes, previous participant number | |
| Enrollment Trigger | 1 |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 16 Apr 2021 14:40:36

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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) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| Condition | CABG |
| Start date (dd MMM yyyy) | 26 FEB 2019 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | 26 FEB 2019 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | FEB 2019 |
| Start Year (derived) | 2019 |
| Stop Month and Year (derived) | FEB 2019 |
| Stop Year (derived) | 2019 |

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| Condition | STENT PLACEMENT |
| Start date (dd MMM yyyy) | UN UNK 2009 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2009 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2009 |
| Start Year (derived) | 2009 |
| Stop Month and Year (derived) | JAN 2009 |
| Stop Year (derived) | 2009 |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| Condition | BILATERAL DECREASED VISUAL ACUITY |
| 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 (5)

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| Condition | CORONARY ARTERY DISEASE |
| Start date (dd MMM yyyy) | UN UNK 2009 |
| 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 2009 |
| Start Year (derived) | 2009 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| Condition | HYPERTRIGLYCERIDEMIA |
| Start date (dd MMM yyyy) | UN FEB 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) | FEB 2010 |
| Start Year (derived) | 2010 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| Condition | HYPERTENSION |
| Start date (dd MMM yyyy) | UN FEB 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) | FEB 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) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| Condition | HYPERCHOLESTEROLEMIA |
| 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 (9)

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| Condition | TYPE II DIABETES |
| Start date (dd MMM yyyy) | UN JAN 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 (11)

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| Condition | CARDIAC EDEMA (CAD) |
| Start date (dd MMM yyyy) | UN FEB 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) | FEB 2019 |
| Start Year (derived) | 2019 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| Condition | LOW TESTOSTERONE |
| 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) | _____ |

US3292312

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:40:36

Generated On: 09 Jun 2021 16:30:59

| | |
|-------------------------------------|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 25 AUG 2020 |
| Time of assessment (00:00-23:59) | 12:50 (24 HR) |
| Vital Signs Date and Time (derived) | 25 AUG 2020 12:50 |
| Height (xxx.x) | 163.6 cm |
| Weight (xxx.x) | 72.9 kg |
| BMI (xxx.x) | 27.23710 kg/m ² |
| BMI units | KG/M2 |
| Temperature (xxx.x) | ND - Not Done |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | ND - Not Done |
| Pulse units | BPM |
| Respiratory Rate (xxx) | ND - Not Done |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | ND - Not Done |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | ND - Not Done |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:11:02

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 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) 23 Feb 2021 14:11:02

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Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☒ No ☐

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 14:11:02

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 25 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT1 |

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Apr 2021 14:40:36

Generated On: 09 Jun 2021 16:30:59

What was the date of randomization? (dd MMM yyyy) 25 AUG 2020

What was the participant's randomization number? 144718

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

| | |
|-------------------------------------|--|
| 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) | 25 AUG 2020 |
| Time of assessment (00:00-23:59) | 13:26 (24 HR) |
| Vital Signs Date and Time (derived) | 25 AUG 2020 13:26 |
| Temperature (xxx.x) | 036.4 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 057 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 020 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 131 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 089 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

| | |
|-------------------------------------|--|
| 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) | 25 AUG 2020 |
| Time of assessment (00:00-23:59) | 15:20 (24 HR) |
| Vital Signs Date and Time (derived) | 25 AUG 2020 15:20 |
| Temperature (xxx.x) | 36.7 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 53 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 144 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 82 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3292312

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

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) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

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) 25 AUG 2020

What was the treatment time? (00:00-23:59) 14:45 (24 HR)

Treatment Date and Time (derived) 25 AUG 2020 14:45

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) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 25 AUG 2020 |
| Collection time (00:00-23:59) | 13:39 (24 HR) |
| Collection date and time (derived) | 25 AUG 2020 13:39 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 25 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 13:52 | 25 AUG 2020 13:52 |
| Nasopharyngeal Swab 2 | No | | |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

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

25 AUG 2020 15:26

PC Open Date & Time

25 AUG 2020 15:05

PC Close Date & Time

25 AUG 2020 17:35

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐
No ☒

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 25 AUG 2020 21:37 |
| PC Open Date & Time | 25 AUG 2020 18:30 |
| PC Close Date & Time | 26 AUG 2020 11:59 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:30:59

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

97.1 °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

26 AUG 2020 14:57

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:30:59

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 15:10

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:30:59

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 22:08

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:30:59

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

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

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

30 AUG 2020 21:57

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:30:59

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

97.5 °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

31 AUG 2020 20:57

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

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

25 AUG 2020 15:27

PC Open Date & Time

25 AUG 2020 15:05

PC Close Date & Time

25 AUG 2020 17:35

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

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

25 AUG 2020 21:37

PC Open Date & Time

25 AUG 2020 18:30

PC Close Date & Time

26 AUG 2020 11:59

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:30:59

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

26 AUG 2020 14:58

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:30:59

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

27 AUG 2020 15:11

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:30:59

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

28 AUG 2020 22:09

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:30:59

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 ☐

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.**

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

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:30:59

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

30 AUG 2020 21:58

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:30:59

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

31 AUG 2020 20:57

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 25 AUG 2020 15:27 |
| PC Open Date & Time | 25 AUG 2020 15:05 |
| PC Close Date & Time | 25 AUG 2020 17:35 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 25 AUG 2020 21:38 |
| PC Open Date & Time | 25 AUG 2020 18:30 |
| PC Close Date & Time | 26 AUG 2020 11:59 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

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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US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 26 AUG 2020 14:59 |
| PC Open Date & Time | 26 AUG 2020 12:00 |
| PC Close Date & Time | 27 AUG 2020 11:59 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 27 AUG 2020 15:12 |
| PC Open Date & Time | 27 AUG 2020 12:00 |
| PC Close Date & Time | 28 AUG 2020 11:59 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 28 AUG 2020 22:09 |
| PC Open Date & Time | 28 AUG 2020 12:00 |
| PC Close Date & Time | 29 AUG 2020 11:59 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:30:59

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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US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:30:59

Yes ☐

PC Time stamp

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 30 AUG 2020 21:58 |
| PC Open Date & Time | 30 AUG 2020 12:00 |
| PC Close Date & Time | 31 AUG 2020 11:59 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

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

63 of 2656

EAB) (1725)

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 31 AUG 2020 20:58 |
| PC Open Date & Time | 31 AUG 2020 12:00 |
| PC Close Date & Time | 01 SEP 2020 11:59 |

US3292312

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292312

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292312

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:10:35

Generated On: 09 Jun 2021 16:30:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292312

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:10:35

Generated On: 09 Jun 2021 16:30:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292312

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:10:35

Generated On: 09 Jun 2021 16:30:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292312

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:10:35

Generated On: 09 Jun 2021 16:30:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292312

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:11:03

Generated On: 09 Jun 2021 16:30:59

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 22 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 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 14:40:36

Generated On: 09 Jun 2021 16:30:59

| | |
|-------------------------------------|---|
| 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) | 22 SEP 2020 |
| Time of assessment (00:00-23:59) | 13:55 (24 HR) |
| Vital Signs Date and Time (derived) | 22 SEP 2020 13:55 |
| Temperature (xxx.x) | 37.0 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 67 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 20 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 94 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 59 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 14:40:36

Generated On: 09 Jun 2021 16:30:59

| | |
|-------------------------------------|--|
| 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) | 22 SEP 2020 |
| Time of assessment (00:00-23:59) | 15:15 (24 HR) |
| Vital Signs Date and Time (derived) | 22 SEP 2020 15:15 |
| Temperature (xxx.x) | 36.8 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 66 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 103 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 69 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:11:03

Generated On: 09 Jun 2021 16:30:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

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

US3292312

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 14:11:03

Generated On: 09 Jun 2021 16:30:59

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) 22 SEP 2020

What was the treatment time? (00:00-23:59) 14:45 (24 HR)

Treatment Date and Time (derived) 22 SEP 2020 14:45

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

US3292312

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 14:11:03

Generated On: 09 Jun 2021 16:30:59

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 22 SEP 2020 |
| Collection time (00:00-23:59) | 14:05 (24 HR) |
| Collection date and time (derived) | 22 SEP 2020 14:05 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 14:11:03

Generated On: 09 Jun 2021 16:30:59

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 22 SEP 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 14:13 | 22 SEP 2020 14:13 |
| Nasopharyngeal Swab 2 | No | | |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:11:03

Generated On: 09 Jun 2021 16:30:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 15:18

PC Open Date & Time

22 SEP 2020 15:05

PC Close Date & Time

22 SEP 2020 17:35

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 22 SEP 2020 21:16 |
| PC Open Date & Time | 22 SEP 2020 18:30 |
| PC Close Date & Time | 23 SEP 2020 11:59 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

23 SEP 2020 20:41

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:30:59

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

24 SEP 2020 20:42

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 20:25

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:30:59

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

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

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:30:59

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

96.9 °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

28 SEP 2020 06:41

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:30:59

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

97.5 °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

28 SEP 2020 22:01

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

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

22 SEP 2020 15:18

PC Open Date & Time

22 SEP 2020 15:05

PC Close Date & Time

22 SEP 2020 17:35

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

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

22 SEP 2020 21:15

PC Open Date & Time

22 SEP 2020 18:30

PC Close Date & Time

23 SEP 2020 11:59

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:30:59

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

90

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

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 20:51

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:30:59

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

24 SEP 2020 20:42

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:30:59

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

25 SEP 2020 20:26

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:30:59

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 ☐

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.**

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

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:30:59

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

28 SEP 2020 06:41

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:30:59

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

28 SEP 2020 22:02

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 22 SEP 2020 15:19 |
| PC Open Date & Time | 22 SEP 2020 15:05 |
| PC Close Date & Time | 22 SEP 2020 17:35 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 22 SEP 2020 21:16 |
| PC Open Date & Time | 22 SEP 2020 18:30 |
| PC Close Date & Time | 23 SEP 2020 11:59 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

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)

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 23 SEP 2020 20:48 |
| PC Open Date & Time | 23 SEP 2020 12:00 |
| PC Close Date & Time | 24 SEP 2020 11:59 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 24 SEP 2020 20:43 |
| PC Open Date & Time | 24 SEP 2020 12:00 |
| PC Close Date & Time | 25 SEP 2020 11:59 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 25 SEP 2020 20:31 |
| PC Open Date & Time | 25 SEP 2020 12:00 |
| PC Close Date & Time | 26 SEP 2020 11:59 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:30:59

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: 09 Jun 2021 16:30:59

Yes ☐

PC Time stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 28 SEP 2020 06:42 |
| PC Open Date & Time | 27 SEP 2020 12:00 |
| PC Close Date & Time | 28 SEP 2020 11:59 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 28 SEP 2020 22:02 |
| PC Open Date & Time | 28 SEP 2020 12:00 |
| PC Close Date & Time | 29 SEP 2020 11:59 |

US3292312

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292312

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292312

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292312

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292312

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292312

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292312

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:11:03

Generated On: 09 Jun 2021 16:30:59

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 22 OCT 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT3 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 14:11:03

Generated On: 09 Jun 2021 16:30:59

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 22 OCT 2020 |
| Time of assessment (00:00-23:59) | 11:17 (24 HR) |
| Vital Signs Date and Time (derived) | 22 OCT 2020 11:17 |
| Temperature (xxx.x) | 36.4 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 59 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 127 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 81 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:11:03

Generated On: 09 Jun 2021 16:30:59

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.

US3292312

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 14:11:03

Generated On: 09 Jun 2021 16:30:59

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 22 OCT 2020 |
| Collection time (00:00-23:59) | 11:30 (24 HR) |
| Collection date and time (derived) | 22 OCT 2020 11:30 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:11:03

Generated On: 09 Jun 2021 16:30:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| TIMEPOINT | DAY 64 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission | 26 OCT 2020 13:20:05 |
| Patient Cloud Open Date & Time | 25 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 29 OCT 2020 23:59 |

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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 checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Date and time of submission | 03 NOV 2020 18:33:56 |
| Patient Cloud Open Date & Time | 01 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 05 NOV 2020 23:59 |

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 11 NOV 2020 10:29:33 |
| Patient Cloud Open Date & Time | 08 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 12 NOV 2020 23:59 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| TIMEPOINT | DAY 89 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 23 NOV 2020 13:03:20 |
| Patient Cloud Open Date & Time | 19 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 23 NOV 2020 23:59 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| TIMEPOINT | DAY 96 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 30 NOV 2020 13:27:37 |
| Patient Cloud Open Date & Time | 26 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 30 NOV 2020 23:59 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 DEC 2020 17:23:45

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 10 DEC 2020 10:38:06 |
| Patient Cloud Open Date & Time | 10 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 14 DEC 2020 23:59 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| TIMEPOINT | DAY 117 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 17 DEC 2020 22:30:53 |
| Patient Cloud Open Date & Time | 17 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 21 DEC 2020 23:59 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 26 DEC 2020 13:09:32 |
| Patient Cloud Open Date & Time | 24 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 28 DEC 2020 23:59 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

01 JAN 2021 18:04:29

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| 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 <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 11 JAN 2021 16:43:01 |
| Patient Cloud Open Date & Time | 07 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 11 JAN 2021 23:59 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

17 JAN 2021 21:56:32

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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 <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 | 21 JAN 2021 14:12:20 |
| Patient Cloud Open Date & Time | 21 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 25 JAN 2021 23:59 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| TIMEPOINT | DAY 159 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 28 JAN 2021 16:21:04 |
| Patient Cloud Open Date & Time | 28 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 01 FEB 2021 23:59 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| TIMEPOINT | DAY 166 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 06 FEB 2021 00:03:43 |
| Patient Cloud Open Date & Time | 04 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 08 FEB 2021 23:59 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

12 FEB 2021 16:36:13

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| TIMEPOINT | DAY 180 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 18 FEB 2021 11:14:50 |
| Patient Cloud Open Date & Time | 18 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 22 FEB 2021 23:59 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

27 FEB 2021 01:43:59

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| TIMEPOINT | DAY 194 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 04 MAR 2021 11:14:45 |
| Patient Cloud Open Date & Time | 04 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 08 MAR 2021 23:59 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| 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 | 11 MAR 2021 07:00:30 |
| Patient Cloud Open Date & Time | 11 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 15 MAR 2021 23:59 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

18 MAR 2021 16:24:17

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

25 MAR 2021 14:37:16

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

03 APR 2021 08:06:01

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

09 APR 2021 14:36:29

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| TIMEPOINT | DAY 236 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 | 18 APR 2021 08:47:45 |
| Patient Cloud Open Date & Time | 15 APR 2021 00:01 |
| Patient Cloud Close Date & Time | 19 APR 2021 23:59 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

22 APR 2021 13:21:31

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| TIMEPOINT | DAY 250 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 | 29 APR 2021 08:19:29 |
| Patient Cloud Open Date & Time | 29 APR 2021 00:01 |
| Patient Cloud Close Date & Time | 03 MAY 2021 23:59 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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 <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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| TIMEPOINT | DAY 271 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| TIMEPOINT | DAY 285 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| TIMEPOINT | DAY 299 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| TIMEPOINT | DAY 306 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

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

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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="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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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 <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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| TIMEPOINT | DAY 383 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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| TIMEPOINT | DAY 390 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

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

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

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Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

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Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

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

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

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

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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 <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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 NOV 2021 00:01 |
| Patient Cloud Close Date & Time | 15 NOV 2021 23:59 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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 <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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

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

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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="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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

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10 MAR 2022 00:01

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14 MAR 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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 ☐ Yes ☐

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

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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 <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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| TIMEPOINT | DAY 656 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 30 JUN 2022 00:01 |
| Patient Cloud Close Date & Time | 04 JUL 2022 23:59 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| TIMEPOINT | DAY 684 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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="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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 21 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 25 JUL 2022 23:59 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 11 AUG 2022 00:01 |
| Patient Cloud Close Date & Time | 15 AUG 2022 23:59 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| TIMEPOINT | DAY 726 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

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

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 22 SEP 2022 00:01 |
| Patient Cloud Close Date & Time | 26 SEP 2022 23:59 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 06 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 10 OCT 2022 23:59 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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 <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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

| 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 <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"/> |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 20 OCT 2022 00:01 |
|--|-------------------|

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 24 OCT 2022 23:59 |
|---|-------------------|

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

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

US3292312

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:30:59

| 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 | | 01 MAR 2021 10:02:01 |

US3292312

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292312

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:11:02

Generated On: 09 Jun 2021 16:30:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292312

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:10:35

Generated On: 09 Jun 2021 16:30:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292312

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:10:35

Generated On: 09 Jun 2021 16:30:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292312

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:10:35

Generated On: 09 Jun 2021 16:30:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292312

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:10:35

Generated On: 09 Jun 2021 16:30:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292312

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:42:19

Generated On: 09 Jun 2021 16:30:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292312

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:42:19

Generated On: 09 Jun 2021 16:30:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292312

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:40:36

Generated On: 09 Jun 2021 16:30:59

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

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

US3292312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:40:36

Generated On: 09 Jun 2021 16:30:59

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) _____

US3292312

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:40:36

Generated On: 09 Jun 2021 16:30:59

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.

US3292312

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:40:36

Generated On: 09 Jun 2021 16:30:59

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 19 MAR 2021 |
| Collection time (00:00-23:59) | 14:10 (24 HR) |
| Collection date and time (derived) | 19 MAR 2021 14:10 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:40:36

Generated On: 09 Jun 2021 16:30:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292312

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 18:34:44

Generated On: 09 Jun 2021 16:30:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292312

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 18:34:44

Generated On: 09 Jun 2021 16:30:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292312

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

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

US3292312

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3292312

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:30:59

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

US3292312

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:30:59

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3292312

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 17:08:26

Generated On: 09 Jun 2021 16:30:59

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 4 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 | UNBLND_DECIDE |

US3292312

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

Form: Unblinding

Data signed: (b) (4) 23 Apr 2021 18:34:44

Generated On: 09 Jun 2021 16:30:59

Date of updated informed consent (dd MMM yyyy) 4 MAR 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 4 MAR 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag ☐

Continuing with mRNA-1273 ☐

US3292312

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 17:08:26

Generated On: 09 Jun 2021 16:30:59

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 4 MAR 2021 |
| Collection time (00:00-23:59) | 11:02 (24 HR) |
| Collection date and time (derived) | 4 MAR 2021 11:02 |

US3292312

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 17:08:26

Generated On: 09 Jun 2021 16:30:59

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 4 MAR 2021 |
| Collection time (00:00 - 23:59) | 11:39 |
| Collection Date and Time (derived) | 4 MAR 2021 11:39 |

US3292312

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Apr 2021 14:40:36

Generated On: 09 Jun 2021 16:30:59

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 15:51:21

Generated On: 09 Jun 2021 16:30:59

| | |
|--|--|
| AEID | USA-US072-2020-MRNA-1273-P30 1000006 |
| Adverse event | STROKE |
| 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) | 25 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) | 25 OCT 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 25 OCT 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 29 OCT 2020 |
| Admitted to ICU? | Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 15:51:21

Generated On: 09 Jun 2021 16:30:59

| | |
|--|---|
| Number of Days in ICU | 2 |
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ | |
| Narrative | |

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 15:51:21

Generated On: 09 Jun 2021 16:30:59

PATIENT CONTACTED STAFF ON 26OCT2020 TO STATE THAT HE HAD BEEN HOSPITALIZED IN THE ICU DUE TO A STROKE THAT OCCURRED ON 25OCT2020. ACCORDING TO THE PATIENT, HE HAD BEEN AT WORK ON THE AFTERNOON OF 25OCT2020 WHEN HE STARTED TO EXPERIENCE LIGHTHEADEDNESS AND BLURRY VISION. PATIENT STATES THAT HE SAT DOWN AND WAITED ABOUT 10 MINUTES BEFORE HE DECIDED TO CALL HIS WIFE TO PICK HIM UP FROM WORK TO TAKE HIM TO THE HOSPITAL. WHILE WAITING FOR HIS WIFE TO PICK HIM UP, PATIENT STATES THAT HE WAS TALKING WITH A COWORKER WHO NOTICED THAT HIS LEFT EYE BEGAN TO DRIFT LEFT, WHILE HIS RIGHT EYE REMAINED STATIONARY. UPON ARRIVAL TO THE ER, PATIENT STATES DOCTORS ORDERED A CT SCAN WHICH SHOWED EVIDENCE OF A STROKE. HOWEVER, PATIENT WAS UNABLE TO PROVIDE ANY INFORMATION AS TO WHERE THE STROKE ORIGINATED OR ITS SEVERITY. PATIENT ALSO STATES THAT HE WAS GIVEN

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 15:51:21

Generated On: 09 Jun 2021 16:30:59

AN ECHOCARDIOGRAM. IN
REGARDS TO MEDICATION,
PATIENT STATES THAT HE WAS
GIVEN AN UNKNOWN BLOOD
THINNER, WHICH HE
ATTRIBUTES TO FEELING
BETTER AND RESTORING HIS
VISION. AS OF TODAY,
26OCT2020, PATIENT IS STILL IN
ICU AWAITING A FOLLOW-UP
MRI AND CT SCAN. NO
FURTHER INFORMATION IS
AVAILABLE AT THIS TIME.
MEDICAL RECORDS WILL BE
REQUESTED AS SOON AS
POSSIBLE.

UPDATE 27OCT2020: PATIENT
STATES HE WAS MOVED OUT
OF ICU TODAY. NEUROLOGIST
EXPLAINED TO PATIENT THAT
THE STROKE SEEMS TO HAVE
TAKEN PLACE IN THE RIGHT
SIDE OF THE OCCIPITAL LOBE,
WITH NO FURTHER
INFORMATION AVAILABLE AT
THIS TIME. FOLLOW-UP MRI
AND CT SCAN INFORMATION
NOT YET AVAILABLE, AS
PATIENT IS TO MEET WITH
NEUROLOGIST TO DISCUSS.
PATIENT ALSO STATES THAT
HIS HEART WENT INTO ATRIAL
FIBRILLATION ON SUNDAY,
25OCT2020, TWICE, SO A
CARDIOLOGY CONSULT HAS

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 15:51:21

Generated On: 09 Jun 2021 16:30:59

BEEN REQUESTED. AS OF
27OCT2020, PATIENT STATES
THAT HE HAS BEEN STARTED
ON BLOOD THINNERS, BUT
NAME OR TYPE IS UNKNOWN.
PATIENT REMAINS
HOSPITALIZED, THOUGH NOW
OUT OF ICU.

| | |
|--|---|
| 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 (2)

Data signed: (b) (4) 22 Apr 2021 15:51:21

Generated On: 09 Jun 2021 16:30:59

| | |
|--|--|
| AEID | |
| Adverse event | CONSTIPATION |
| 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) | 25 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) | 29 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 15:51:21

Generated On: 09 Jun 2021 16:30:59

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

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 15:51:21

Generated On: 09 Jun 2021 16:30:59

| | |
|--|--|
| AEID | |
| Adverse event | NAUSEA |
| 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) | 25 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) | 29 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 15:51:21

Generated On: 09 Jun 2021 16:30:59

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 15:51:21

Generated On: 09 Jun 2021 16:30:59

| | |
|--|--|
| AEID | |
| Adverse event | UTI |
| 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) | 29 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 15:51:21

Generated On: 09 Jun 2021 16:30:59

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 15:51:21

Generated On: 09 Jun 2021 16:30:59

| | |
|--|--|
| AEID | |
| Adverse event | GERD |
| 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) | 25 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) | 29 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 15:51:21

Generated On: 09 Jun 2021 16:30:59

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 22 Apr 2021 15:51:21

Generated On: 09 Jun 2021 16:30:59

AEID

Adverse event

AROUSAL DIFFICULTY

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)

25 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)

29 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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 22 Apr 2021 15:51:21

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

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 22 Apr 2021 15:51:21

Generated On: 09 Jun 2021 16:30:59

AEID

Adverse event

ATRIAL FIBRILLATION

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)

25 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)

25 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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 22 Apr 2021 15:51:21

Generated On: 09 Jun 2021 16:30:59

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

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 22 Apr 2021 15:51:21

Generated On: 09 Jun 2021 16:30:59

AEID

Adverse event

ACUTE ON CHRONIC SYSTOLIC
AND DIASTOLIC DYSFUNCTION

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)

25 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)

25 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 ☐

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 22 Apr 2021 15:51:21

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| | |
|--|---|
| Number of Days in ICU | |
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input 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 | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 14:10:34

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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) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

Name of Medication BABY ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication HEART HEALTH

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:51:23

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2010 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 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 (2)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2010 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 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) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

Name of Medication CERVEDILOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

| | | |
|--|--------------------------|----------------------------------|
| | 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 FEB 2019 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | | 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) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION/CARDIAC
EDEMA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 15:51:23

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

Name of Medication EPLERENONE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

3X A WEEK

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 15:51:23

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 30 JUN 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) | | _____ |
| Interval Dosage Unit Number (derived) | | _____ |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

Name of Medication PLAVIX

Prophylaxis Yes ☐
No ☒

Indication CAD

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2010 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 2 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 15:51:23

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Name of Medication SYNJARDY

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 15:51:23

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 15:51:23

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Name of Medication VASCEPA/ICOSAPENT

Prophylaxis Yes ☐
No ☒

Indication HYPERTRIGLYCERIDEMIA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

| | | |
|--|--------------------------|----------------------------------|
| | 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 FEB 2019 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | | 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 (9)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

Name of Medication BUMETANIDE

Prophylaxis Yes ☐
No ☒

Indication CARDIAC EDEMA

Dose per administration 0.05

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

4X WEEK

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 15:51:23

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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 MAR 2019 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 15:51:23

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Name of Medication APIXABAN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR STROKE

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 15:51:23

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 30 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) | | 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 (11)

Data signed: (b) (4) 22 Apr 2021 15:51:23

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Name of Medication TICAGRELOR

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR STROKE

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 (11)

Data signed: (b) (4) 22 Apr 2021 15:51:23

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 30 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) | | 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 (12)

Data signed: (b) (4) 22 Apr 2021 15:51:23

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Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication GERD

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

Q12H

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 15:51:23

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input checked="" type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 25 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) | | 29 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 15:51:23

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Name of Medication MAGNESIUM HYDROXIDE

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 15:51:23

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| | | |
|--|--------------------------|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 25 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) | | 29 OCT 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 15:51:23

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Name of Medication BISACODYL

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

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 (14)

Data signed: (b) (4) 22 Apr 2021 15:51:23

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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 checked="" type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 25 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) | | 29 OCT 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 15:51:23

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Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication NAUSEA

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 15:51:23

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| | | |
|--|--------------------------|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input checked="" type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 25 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) | | 29 OCT 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

Name of Medication NALOXONE

Prophylaxis Yes ☐
No ☒

Indication AROUSAL DIFFICULTY

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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) 22 Apr 2021 15:51:23

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| | | |
|--|--------------------------|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input checked="" type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 25 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) | | 29 OCT 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐
No ☒

Indication UTI

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 15:51:23

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| | | |
|--|--------------------------------------|----------------------------------|
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input checked="" type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 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) | 29 OCT 2020 | |
| 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"/> | |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

Name of Medication VANCOMYCIN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS OF INFECTION

Dose per administration 250

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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US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

| | | |
|--|---|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input checked="" type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 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) | 29 OCT 2020 | |
| Was this medication taken for solicited event? | Yes <input type="checkbox"/> | |
| | No <input checked="" type="checkbox"/> | |
| Separate Dosage Number (derived) | 3 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 <input type="checkbox"/> | |
| | 803 <input type="checkbox"/> | |
| | 804 <input checked="" type="checkbox"/> | |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

| | |
|--------------------------------|--|
| Name of Medication | TPA |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | ACUTE CVA |
| Dose per administration | UNKNOWN |
| Dose unit | mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/> |
| If dose unit is Other, specify | UNKNOWN |
| Frequency | once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/> |
| If frequency is Other, specify | |
| Route of administration | Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> |

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

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

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

Name of Medication VANCOMYCIN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS OF INFECTION

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

| | | |
|--|--------------------------|-------------------------------------|
| | 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 checked="" type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN 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) | | UN 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 (21)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

Name of Medication ISOVUE-370

Prophylaxis Yes ☐
No ☒

Indication ACUTE CVA (CTA)

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input checked="" type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 25 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) | 25 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS (INFECTION)

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

| | | |
|--|-------------------------------------|----------------------------------|
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input checked="" type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 25 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) | 29 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"/> | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input checked="" type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 14 NOV 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 14 NOV 2020 |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

Name of Medication TESTOSTERONE

Prophylaxis Yes ☐
No ☒

Indication LOW TESTOSTERONE

Dose per administration 1

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

If dose unit is Other, specify CC

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

If frequency is Other, specify EVERY OTHER WEEK

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

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

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input checked="" type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 30 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) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

Name of Medication ALTEPLASE/ACTIVASE

Prophylaxis Yes ☐
No ☒

Indication STROKE

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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 (25)

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:30:59

| | | |
|--|-------------------------------------|----------------------------------|
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input checked="" type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 25 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) | 25 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"/> | |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 14:10:34

Generated On: 09 Jun 2021 16:30:59

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:30:59

| Procedure/Surgery date (dd MMM yyyy) | Procedure/Surgery | Indication | If indication is Other, specify |
|---|-------------------|---------------|---------------------------------|
| 25 OCT 2020 | CTA-HEAD AND NECK | Diagnostic | |
| 26 OCT 2020 | MRI | Diagnostic | |
| 27 OCT 2020 | CAROTID DOPPLER | Diagnostic | |
| 26 OCT 2020 | HEAD CT | Diagnostic | |
| 25 OCT 2020 | HEAD CT | Diagnostic | |
| 30 DEC 2020 | AICD INSERTION | Adverse Event | |
| 25 OCT 2020 | CHEST X-RAY | Diagnostic | |
| 28 OCT 2020 | TRANSESOPHAGEAL | Diagnostic | |
| 26 OCT 2020 | ECHOCARDIOGRAM | Adverse Event | |

US3292312

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:30:59

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

US3292312

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:30:59

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 ☐

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 14:40:36

Generated On: 09 Jun 2021 16:30:59

| | |
|--|--|
| SAEID | USA-US072-2020-MRNA-1273-P301000006 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input 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 | DOUGLAS |
| Investigator's Last Name | DENHAM |
| Site Address: Street | 7940 FLOYD CURL DRIVE |
| Site Address: City | SAN ANTONIO |
| Site Address: State | |
| Site Address: Postal Code | 78229 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 7 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 14:40:36

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| SAEID | USA-US072-2020-MRNA-1273-P301000006 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input 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 | DOUGLAS |
| Investigator's Last Name | DENHAM |
| Site Address: Street | 7940 FLOYD CURL DRIVE |
| Site Address: City | SAN ANTONIO |
| Site Address: State | |
| Site Address: Postal Code | 78229 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 7 |
| Date of submission (Pre-filled from custom function) | 27/OCT/2020 14:25 |
| 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 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 14:40:36

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| SAEID | USA-US072-2020-MRNA-1273-P301000006 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input 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 | DOUGLAS |
| Investigator's Last Name | DENHAM |
| Site Address: Street | 7940 FLOYD CURL DRIVE |
| Site Address: City | SAN ANTONIO |
| Site Address: State | |
| Site Address: Postal Code | 78229 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 7 |
| Date of submission (Pre-filled from custom function) | 28/OCT/2020 10:47 |
| 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 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 14:40:36

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| SAEID | USA-US072-2020-MRNA-1273-P301000006 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input 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 | DOUGLAS |
| Investigator's Last Name | DENHAM |
| Site Address: Street | 7940 FLOYD CURL DRIVE |
| Site Address: City | SAN ANTONIO |
| Site Address: State | |
| Site Address: Postal Code | 78229 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 7 |
| Date of submission (Pre-filled from custom function) | 25/NOV/2020 14:56 |
| 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 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 16 Apr 2021 14:40:36

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| SAEID | USA-US072-2020-MRNA-1273-P301000006 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input 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 | DOUGLAS |
| Investigator's Last Name | DENHAM |
| Site Address: Street | 7940 FLOYD CURL DRIVE |
| Site Address: City | SAN ANTONIO |
| Site Address: State | |
| Site Address: Postal Code | 78229 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 7 |
| Date of submission (Pre-filled from custom function) | 14/JAN/2021 10:14 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) 16 Apr 2021 14:40:36

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| SAEID | USA-US072-2020-MRNA-1273-P301000006 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input 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 | DOUGLAS |
| Investigator's Last Name | DENHAM |
| Site Address: Street | 7940 FLOYD CURL DRIVE |
| Site Address: City | SAN ANTONIO |
| Site Address: State | |
| Site Address: Postal Code | 78229 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 7 |
| Date of submission (Pre-filled from custom function) | 10/FEB/2021 09:11 |
| 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 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Data signed: (b) (4) 16 Apr 2021 14:40:36

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| SAEID | USA-US072-2020-MRNA-1273-P301000006 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input 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 | DOUGLAS |
| Investigator's Last Name | DENHAM |
| Site Address: Street | 7940 FLOYD CURL DRIVE |
| Site Address: City | SAN ANTONIO |
| Site Address: State | |
| Site Address: Postal Code | 78229 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 7 |
| Date of submission (Pre-filled from custom function) | 12/FEB/2021 14:26 |
| 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 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form (7)

Data signed: (b) (4) 16 Apr 2021 14:40:36

Generated On: 09 Jun 2021 16:30:59

| | |
|---|--|
| SAEID | USA-US072-2020-MRNA-1273-P301000006 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input 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 | DOUGLAS |
| Investigator's Last Name | DENHAM |
| Site Address: Street | 7940 FLOYD CURL DRIVE |
| Site Address: City | SAN ANTONIO |
| Site Address: State | |
| Site Address: Postal Code | 78229 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 7 |
| Date of submission (Pre-filled from custom function) | 25/MAR/2021 09:07 |
| 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

US3292312 (Prod: Clinical Trials of Texas, Inc)

US3292312

Form: Participant Creation

Generated On: 09 Jun 2021 16:30:59

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 21:22:48 |
| User entered 'US3292312' | RWS_ENDPOINT ENDPOINT (b) (4) | 25 Aug 2020 19:09:26 |

US3292312

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:30:59

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 29 Jan 2021 14:36:14 |
| User entered 'Yes (Y)' | | 27 Aug 2020 16:11:19 |

US3292312

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 29 Jan 2021 14:36:14 |
| User entered '25 AUG 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 25 Aug 2020 19:09:27 |

US3292312

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 14:36:14 |
| User entered 'Clinic (Clinic)' | | 27 Aug 2020 16:11:19 |

US3292312

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:30:59

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'SCRN' | System | 27 Aug 2020 16:11:19 |

US3292312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:30:59

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:10:02 |
| User closed query 'Please provide source' (Site from CRA). | | 16 Apr 2021 18:09:54 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| Query 'Please provide source' answered with 'on med hx; uploaded to eSource' (Site from CRA). | (b) (4) | |
| | Dawn Killian (b) (4) | 23 Mar 2021 18:57:36 |
| User opened query 'Please provide source' (Site from CRA). | (b) (4) | |
| | (b) (4), (b) (6) | 29 Jan 2021 14:57:58 |
| User entered (b) (6) 1963' | RWS_ENDPOINT ENDPOINT (b) (4) | 25 Aug 2020 19:09:28 |

US3292312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:30:59

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:10:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| User entered '56' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:11:35 |

US3292312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:30:59

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'YEARS' | System | 27 Aug 2020 16:11:35 |

US3292312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:30:59

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered '56' | System | 25 Aug 2020 20:10:45 |

US3292312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:30:59

[Sex](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:10:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| User entered 'Male (M)' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:11:35 |

US3292312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:30:59

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:10:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| User entered 'Hispanic or Latino (HISPANIC OR LATINO)' | (b) (4), (b) (6) | 27 Aug 2020 16:11:35 |

US3292312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:30:59

[White](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:10:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| User entered 'l' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:11:35 |

US3292312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:30:59

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:10:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:11:35 |

US3292312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:30:59

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:10:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:11:35 |

US3292312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:30:59

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:10:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:11:35 |

US3292312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:30:59

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:10:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:11:35 |

US3292312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:30:59

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:10:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:11:35 |

US3292312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:30:59

If race is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:10:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:11:35 |

US3292312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:30:59

[Unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:10:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:11:35 |

US3292312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:30:59

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:10:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:11:35 |

US3292312

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:30:59

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 14:59:41 |
| User entered '25 Aug 2020' | (b) (4), (b) (6) | 25 Aug 2020 20:10:45 |

US3292312

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'Aug 2020' | System | 25 Aug 2020 20:10:45 |

US3292312

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered '2020' | System | 25 Aug 2020 20:10:45 |

US3292312

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:30:59

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 14:59:41 |
| User entered 'Amendment 3 (3)' | (b) (4), (b) (6) | 25 Aug 2020 20:10:45 |

US3292312

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 14:59:41 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Aug 2020 20:10:45 |

US3292312

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 14:59:41 |
| User entered empty. | (b) (4), (b) (6) | 25 Aug 2020 20:10:45 |

US3292312

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:30:59

[If reason for screen fail is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 14:59:41 |
| User entered empty. | (b) (4), (b) (6) | 25 Aug 2020 20:10:45 |

US3292312

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:30:59

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 29 Jan 2021 14:59:41 |
| User entered 'No (N)' | | 25 Aug 2020 20:10:45 |

US3292312

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:30:59

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 29 Jan 2021 14:59:41 |
| User entered empty. | RWS_ENDPOINT ENDPOINT (b) (4) | 25 Aug 2020 19:09:27 |

US3292312

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:30:59

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'l' | System | 25 Aug 2020 20:11:08 |

US3292312

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 14:59:47 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Aug 2020 20:11:08 |

US3292312

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:30:59

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Apr 2021 21:12:09 |
| User closed query 'Please provide medical history source' (Site from CRA). | (b) (4) | 05 Apr 2021 21:12:07 |
| Query 'Please provide medical history source' answered with 'uploaded to e-Source' (Site from CRA). | Dawn Killian (b) (4) | 23 Mar 2021 18:57:15 |
| User opened query 'Please provide medical history source' (Site from CRA). | (b) (4), (b) (6) | 29 Jan 2021 15:02:51 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 29 Jan 2021 15:02:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:02:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 16:11:40 |

US3292312

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:30:59

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User coded data point as SOC: Surgical and medical procedures, HLT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary artery bypass, LLT: CABG - version MedDRA\23.0. | (b) (4) Coder Import (b) (4) | 27 Aug 2020 19:32:39 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 27 Aug 2020 19:32:39 |
| Data point term sent to Coder | System | 27 Aug 2020 16:12:33 |
| User entered 'CABG' | (b) (4), (b) (6) | 27 Aug 2020 16:12:08 |

US3292312

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '26 Feb 2019' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:12:08 |

US3292312

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 16:12:08 |

US3292312

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:30:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:12:08 |

US3292312

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '26 Feb 2019' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:12:08 |

US3292312

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:30:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:12:08 |

US3292312

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'Feb 2019' | System | 27 Aug 2020 16:12:08 |

US3292312

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered '2019' | System | 27 Aug 2020 16:12:08 |

US3292312

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'Feb 2019' | System | 27 Aug 2020 16:12:08 |

US3292312

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered '2019' | System | 27 Aug 2020 16:12:08 |

US3292312

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:30:59

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Stent placement, LLT: Stent placement - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 27 Aug 2020 19:32:39 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 19:32:39 |
| Data point term sent to Coder | System | 27 Aug 2020 16:12:34 |
| User entered 'STENT PLACEMENT' | (b) (4), (b) (6) | 27 Aug 2020 16:12:27 |

US3292312

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'UN UNK 2009' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:12:27 |

US3292312

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:12:27 |

US3292312

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:30:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:12:27 |

US3292312

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'UN UNK 2009' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:12:27 |

US3292312

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:30:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:12:27 |

US3292312

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'Jan 2009' | System | 27 Aug 2020 16:12:27 |

US3292312

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered '2009' | System | 27 Aug 2020 16:12:27 |

US3292312

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'Jan 2009' | System | 27 Aug 2020 16:12:27 |

US3292312

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered '2009' | System | 27 Aug 2020 16:12:27 |

US3292312

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:30:59

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 27 Aug 2020 19:32:44 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 19:32:44 |
| Data point term sent to Coder | System | 27 Aug 2020 16:13:36 |
| User entered 'VASECTOMY' | (b) (4), (b) (6) | 27 Aug 2020 16:12:44 |

US3292312

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'UN UNK 1995' | (b) (4), (b) (6) | 27 Aug 2020 16:12:44 |

US3292312

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:12:44 |

US3292312

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:30:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 16:12:44 |

US3292312

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'UN UNK 1995' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:12:44 |

US3292312

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:30:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:12:44 |

US3292312

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'Jan 1995' | System | 27 Aug 2020 16:12:44 |

US3292312

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered '1995' | System | 27 Aug 2020 16:12:44 |

US3292312

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'Jan 1995' | System | 27 Aug 2020 16:12:44 |

US3292312

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered '1995' | System | 27 Aug 2020 16:12:44 |

US3292312

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:30:59

Condition

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:12:07 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User closed query 'Per DM CLR: Please update the condition to include the laterality of Decreased Visual Acuity (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 08 Oct 2020 14:32:50 |
| User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Visual acuity reduced, LLT: Visual acuity decreased - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 22 Sep 2020 21:31:48 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 22 Sep 2020 21:31:48 |
| Data point term sent to Coder | System | 22 Sep 2020 21:31:19 |
| Query 'Per DM CLR: Please update the condition to include the laterality of Decreased Visual Acuity (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM). | Dawn Killian (b) (4) (b) (4) | 22 Sep 2020 21:31:08 |
| Coding entries removed. | Dawn Killian (b) (4) (b) (4) | 22 Sep 2020 21:31:04 |
| User entered 'bilateral DECREASED VISUAL ACUITY' reason for change: Data Entry Error | Dawn Killian (b) (4) (b) (4) | 22 Sep 2020 21:31:04 |
| User opened query 'Per DM CLR: Please update the condition to include the laterality of Decreased Visual Acuity (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM). | (b) (4), (b) (6) | 16 Sep 2020 15:06:02 |

US3292312

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:30:59

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Visual acuity reduced, LLT: Visual acuity decreased - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 19:32:45 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 19:32:45 |
| Data point term sent to Coder | System | 27 Aug 2020 16:13:36 |
| User entered 'DECREASED VISUAL ACUITY' | (b) (4), (b) (6) | 27 Aug 2020 16:13:00 |

US3292312

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'UN UNK 2019' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:13:00 |

US3292312

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 16:13:00 |

US3292312

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:30:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:13:00 |

US3292312

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:13:00 |

US3292312

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:30:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:13:00 |

US3292312

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'Jan 2019' | System | 27 Aug 2020 16:13:00 |

US3292312

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered '2019' | System | 27 Aug 2020 16:13:00 |

US3292312

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered empty. | System | 27 Aug 2020 16:13:00 |

US3292312

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered empty. | System | 27 Aug 2020 16:13:00 |

US3292312

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:30:59

[Condition](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0. | (b) (4) Coder Import (b) (4) (b) (4) | 27 Aug 2020 19:32:44 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 27 Aug 2020 19:32:44 |
| Data point term sent to Coder | System | 27 Aug 2020 16:13:36 |
| User entered 'CORONARY ARTERY DISEASE' | (b) (4), (b) (6) | 27 Aug 2020 16:13:28 |

US3292312

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'UN UNK 2009' | (b) (4), (b) (6) | 27 Aug 2020 16:13:28 |

US3292312

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 16:13:28 |

US3292312

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:30:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 16:13:28 |

US3292312

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:13:28 |

US3292312

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:30:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 16:13:28 |

US3292312

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'Jan 2009' | System | 27 Aug 2020 16:13:28 |

US3292312

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered '2009' | System | 27 Aug 2020 16:13:28 |

US3292312

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered empty. | System | 27 Aug 2020 16:13:28 |

US3292312

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered empty. | System | 27 Aug 2020 16:13:28 |

US3292312

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:30:59

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated triglycerides, PT: Hypertriglyceridaemia, LLT: Hypertriglyceridemia - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 27 Aug 2020 19:32:50 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 19:32:50 |
| Data point term sent to Coder | System | 27 Aug 2020 16:14:37 |
| User entered 'HYPERTRIGLYCERIDEMIA' | (b) (4), (b) (6) | 27 Aug 2020 16:13:53 |

US3292312

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'UN Feb 2010' | (b) (4), (b) (6) | 27 Aug 2020 16:13:53 |

US3292312

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 16:13:53 |

US3292312

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:30:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 16:13:53 |

US3292312

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:13:53 |

US3292312

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:30:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 16:13:53 |

US3292312

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'Feb 2010' | System | 27 Aug 2020 16:13:53 |

US3292312

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered '2010' | System | 27 Aug 2020 16:13:53 |

US3292312

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered empty. | System | 27 Aug 2020 16:13:53 |

US3292312

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered empty. | System | 27 Aug 2020 16:13:53 |

US3292312

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:30:59

[Condition](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 27 Aug 2020 19:32:48 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 19:32:48 |
| Data point term sent to Coder | System | 27 Aug 2020 16:14:40 |
| User entered 'HYPERTENSION' | (b) (4), (b) (6) | 27 Aug 2020 16:14:09 |

US3292312

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'UN Feb 2019' | (b) (4), (b) (6) | 27 Aug 2020 16:14:09 |

US3292312

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 16:14:09 |

US3292312

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:30:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 16:14:09 |

US3292312

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:14:09 |

US3292312

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:30:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 16:14:09 |

US3292312

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'Feb 2019' | System | 27 Aug 2020 16:14:09 |

US3292312

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered '2019' | System | 27 Aug 2020 16:14:09 |

US3292312

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered empty. | System | 27 Aug 2020 16:14:09 |

US3292312

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered empty. | System | 27 Aug 2020 16:14:09 |

US3292312

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:30:59

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 27 Aug 2020 19:32:50 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 19:32:50 |
| Data point term sent to Coder | System | 27 Aug 2020 16:14:38 |
| User entered 'HYPERCHOLESTEROLEMIA' | (b) (4), (b) (6) | 27 Aug 2020 16:14:28 |

US3292312

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'UN UNK 2010' | (b) (4), (b) (6) | 27 Aug 2020 16:14:28 |

US3292312

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 16:14:28 |

US3292312

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:30:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 16:14:28 |

US3292312

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:14:28 |

US3292312

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:30:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 16:14:28 |

US3292312

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'Jan 2010' | System | 27 Aug 2020 16:14:28 |

US3292312

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered '2010' | System | 27 Aug 2020 16:14:28 |

US3292312

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered empty. | System | 27 Aug 2020 16:14:28 |

US3292312

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered empty. | System | 27 Aug 2020 16:14:28 |

US3292312

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:30:59

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Diverticulitis - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 27 Aug 2020 19:32:58 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 19:32:58 |
| Data point term sent to Coder | System | 27 Aug 2020 16:15:44 |
| User entered 'DIVERTICULITIS' | (b) (4), (b) (6) | 27 Aug 2020 16:14:53 |

US3292312

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'UN UNK 2015' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:14:53 |

US3292312

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:14:53 |

US3292312

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:30:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 16:14:53 |

US3292312

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'UN UNK 2015' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:14:53 |

US3292312

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:30:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 16:14:53 |

US3292312

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'Jan 2015' | System | 27 Aug 2020 16:14:53 |

US3292312

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered '2015' | System | 27 Aug 2020 16:14:53 |

US3292312

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'Jan 2015' | System | 27 Aug 2020 16:14:53 |

US3292312

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered '2015' | System | 27 Aug 2020 16:14:53 |

US3292312

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:30:59

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| 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 II diabetes mellitus - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 27 Aug 2020 19:32:58 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 19:32:58 |
| Data point term sent to Coder | System | 27 Aug 2020 16:15:45 |
| User entered 'TYPE II DIABETES' | (b) (4), (b) (6) | 27 Aug 2020 16:15:07 |

US3292312

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'UN Jan 2019' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:15:07 |

US3292312

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:15:07 |

US3292312

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:30:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:15:07 |

US3292312

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:15:07 |

US3292312

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:30:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:15:07 |

US3292312

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'Jan 2019' | System | 27 Aug 2020 16:15:07 |

US3292312

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered '2019' | System | 27 Aug 2020 16:15:07 |

US3292312

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered empty. | System | 27 Aug 2020 16:15:07 |

US3292312

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered empty. | System | 27 Aug 2020 16:15:07 |

US3292312

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:30:59

Condition

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User closed query 'Per DM CLR: Please specify the location of Edema. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 08 Oct 2020 14:33:16 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema due to cardiac disease, LLT: Cardiac induced edema - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 04 Oct 2020 04:59:36 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 04 Oct 2020 04:59:36 |
| Data point term sent to Coder | System | 23 Sep 2020 18:34:15 |
| User closed query 'CDM-Coding: Please clarify this clinical event with more details if it is 1. Cardiac induced edema or 2. Cardiogenic pulmonary edema Or Something else and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System). | System | 23 Sep 2020 18:34:13 |
| Query 'CDM-Coding: Please clarify this clinical event with more details if it is 1. Cardiac induced edema or 2. Cardiogenic pulmonary edema Or Something else and amend /update the term accordingly in the diagnosis field to enable coding. ' answered with 'updated' (Site from System). | Dawn Killian (b) (4) (b) (4) | 23 Sep 2020 18:34:13 |
| User entered 'CARDIAC EDEMA (CAD)' reason for change: Data Entry Error | Dawn Killian (b) (4) (b) (4) | 23 Sep 2020 18:34:07 |
| User opened query 'CDM-Coding: Please clarify this clinical event with more details if it is 1. Cardiac induced edema or 2. Cardiogenic pulmonary edema Or Something else and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System). | Coder Import (b) (4) | 23 Sep 2020 08:11:44 |
| Data point term sent to Coder | System | 22 Sep 2020 21:32:20 |

US3292312

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:30:59

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Query 'Per DM CLR: Please specify the location of Edema. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM). Coding entries removed. | Dawn Killian (b) (4) | 22 Sep 2020 21:31:25 |
| | Dawn Killian (b) (4) | 22 Sep 2020 21:31:20 |
| User entered 'cardiac EDEMA' reason for change: Data Entry Error | Dawn Killian (b) (4) | 22 Sep 2020 21:31:20 |
| User opened query 'Per DM CLR: Please specify the location of Edema. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM). | (b) (4), (b) (6) | 16 Sep 2020 15:06:13 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema, LLT: Edema - version MedDRA\23.0. | Coder Import (b) (4) | 27 Aug 2020 19:32:58 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 27 Aug 2020 19:32:58 |
| Data point term sent to Coder | System | 27 Aug 2020 16:15:45 |
| User entered 'EDEMA' | (b) (4), (b) (6) | 27 Aug 2020 16:15:26 |

US3292312

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'UN Feb 2019' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:15:26 |

US3292312

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:15:26 |

US3292312

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:30:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:15:26 |

US3292312

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:15:26 |

US3292312

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:30:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 16:15:26 |

US3292312

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'Feb 2019' | System | 27 Aug 2020 16:15:26 |

US3292312

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered '2019' | System | 27 Aug 2020 16:15:26 |

US3292312

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered empty. | System | 27 Aug 2020 16:15:26 |

US3292312

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered empty. | System | 27 Aug 2020 16:15:26 |

US3292312

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:30:59

Condition

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User coded data point as SOC: Investigations, HLGT: Endocrine investigations (incl sex hormones), HLT: Reproductive hormone analyses, PT: Blood testosterone decreased, LLT: Testosterone low - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 27 Aug 2020 19:32:57 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 19:32:57 |
| Data point term sent to Coder | System | 27 Aug 2020 16:15:46 |
| User entered 'LOW TESTOSTERONE' | (b) (4), (b) (6) | 27 Aug 2020 16:15:43 |

US3292312

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'UN UNK 2019' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:15:43 |

US3292312

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:15:43 |

US3292312

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:30:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 16:15:43 |

US3292312

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:15:43 |

US3292312

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:30:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| DataPoint Verified. | | 16 Apr 2021 18:13:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 16:15:43 |

US3292312

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'Jan 2019' | System | 27 Aug 2020 16:15:43 |

US3292312

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered '2019' | System | 27 Aug 2020 16:15:43 |

US3292312

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered empty. | System | 27 Aug 2020 16:15:43 |

US3292312

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered empty. | System | 27 Aug 2020 16:15:43 |

US3292312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:07:03 |
| User entered 'Yes (Y)' | | 27 Aug 2020 16:16:23 |

US3292312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:07:04 |
| User entered '25 Aug 2020' | | 27 Aug 2020 16:16:23 |

US3292312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:07:07 |
| User entered '12:50' | | 27 Aug 2020 16:16:23 |

US3292312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered '25 Aug 2020 12:50' | System | 27 Aug 2020 16:16:23 |

US3292312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

Height (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:07:08 |
| User entered '163.6' cm | | 27 Aug 2020 16:16:23 |
| DataPoint set to visible. | System | 25 Aug 2020 20:11:08 |

US3292312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:07:10 |
| User entered '72.9' kg | | 27 Aug 2020 16:16:23 |
| DataPoint set to visible. | System | 25 Aug 2020 20:11:08 |

US3292312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

BMI (xxx.x)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User closed query 'Please confirm value with source' (Site from CRA). | (b) (4) | 05 Apr 2021 21:12:32 |
| Query 'Please confirm value with source' answered with 'updated source' (Site from CRA). | Dawn Killian (b) (4) | 23 Mar 2021 18:55:36 |
| User opened query 'Please confirm value with source' (Site from CRA). | (b) (4), (b) (6) | 29 Jan 2021 15:05:56 |
| Amendment Manager: User entered '27.23710' | System | 17 Sep 2020 00:02:27 |
| User entered '27.2' | System | 27 Aug 2020 16:16:23 |
| DataPoint set to visible. | System | 25 Aug 2020 20:11:08 |

US3292312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'kg/m2' | System | 27 Aug 2020 16:16:23 |
| DataPoint set to visible. | System | 25 Aug 2020 20:11:08 |

US3292312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:07:12 |
| User closed query 'Per CDM: As per CCG, "Not Done" to be updated in the text field. ' (Site from DM). | (b) (4), (b) (6) | 27 Jan 2021 12:09:09 |
| Query 'Per CDM: As per CCG, "Not Done" to be updated in the text field. ' answered with 'updated' (Site from DM). | Dawn Killian (b) (4) | 25 Jan 2021 19:14:57 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 25 Jan 2021 19:14:49 |
| User opened query 'Per CDM: As per CCG, "Not Done" to be updated in the text field. ' (Site from DM). | (b) (4), (b) (6) | 06 Jan 2021 08:41:43 |
| User closed query 'Data is required. Please provide.' (Site from System). | | 30 Dec 2020 19:30:17 |
| Query 'Data is required. Please provide.' answered with 'N/A' (Site from System). | | 30 Dec 2020 17:43:34 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 30 Dec 2020 17:43:23 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 30 Dec 2020 17:43:23 |
| User entered missing code ND - Not Done. | | 27 Aug 2020 16:16:23 |

US3292312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:07:13 |
| User closed query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' (Site from DM). | (b) (4), (b) (6) | 23 Dec 2020 13:36:50 |
| Query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' answered with 'updated' (Site from DM). | Dawn Killian (b) (4) | 21 Dec 2020 19:50:21 |
| User entered empty; reason for change Data Entry Error | (b) (4) | 21 Dec 2020 19:50:15 |
| User opened query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' (Site from DM). | (b) (4), (b) (6) | 14 Dec 2020 17:22:01 |
| User entered 'Other (Other)' | | 7 Aug 2020 16:16:23 |

US3292312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:07:15 |
| User closed query 'Per CDM: Please remove the data as this field should be "blank". | (b) (4), (b) (6) | 30 Dec 2020 19:30:14 |
| ' (Site from DM). | | |
| Query 'Per CDM: Please remove the data as this field should be "blank". | | 30 Dec 2020 17:43:06 |
| ' answered with 'Completed' (Site from DM). | | |
| User entered empty; reason for change Data Entry Error | | 30 Dec 2020 17:42:59 |
| User opened query 'Per CDM: Please remove the data as this field should be "blank". | | 23 Dec 2020 13:37:00 |
| ' (Site from DM). | | |
| User entered missing code ND - Not Done. | | 27 Aug 2020 16:16:23 |

US3292312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

Pulse (xxx)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:07:16 |
| User closed query '□ Per CDM: If participant was Screened and Dose on same day. Pulse, Respiratory Rate, Systolic and Diastolic Blood Pressure should be recorded as Not Done THEN Units should be left blank.' (Site from DM). | | 31 Dec 2020 19:24:23 |
| Query '□ Per CDM: If participant was Screened and Dose on same day. Pulse, Respiratory Rate, Systolic and Diastolic Blood Pressure should be recorded as Not Done THEN Units should be left blank.' answered with 'done' (Site from DM). | Kevin Martinez (b) (4) (b) (4) | 31 Dec 2020 17:40:28 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Kevin Martinez (b) (4) (b) (4) | 31 Dec 2020 17:40:23 |
| User opened query '□ Per CDM: If participant was Screened and Dose on same day. Pulse, Respiratory Rate, Systolic and Diastolic Blood Pressure should be recorded as Not Done THEN Units should be left blank.' (Site from DM). | (b) (4), (b) (6) | 30 Dec 2020 22:20:50 |
| User closed query 'Per CDM: If participant was Screened and Dose on same day. Pulse, Respiratory Rate, Systolic and Diastolic Blood Pressure should be recorded as Not Done.' (Site from DM). | (b) (4), (b) (6) | 30 Dec 2020 22:20:50 |
| Query 'Per CDM: If participant was Screened and Dose on same day. Pulse, Respiratory Rate, Systolic and Diastolic Blood Pressure should be recorded as Not Done.' answered with 'Previous query stated to leave blank. Please advise.' (Site from DM). | (b) (4), (b) (6) | 30 Dec 2020 19:34:10 |
| User opened query 'Per CDM: If participant was Screened and Dose on same day. Pulse, Respiratory Rate, Systolic and Diastolic Blood Pressure should be recorded as Not Done.' (Site from DM). | (b) (4), (b) (6) | 30 Dec 2020 19:30:46 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 30 Dec 2020 19:30:08 |
| Query 'Data is required. Please provide.' answered with 'N/A' (Site from System). | (b) (4), (b) (6) | 30 Dec 2020 17:43:40 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 30 Dec 2020 17:43:23 |

US3292312

Folder: Screening

Form: Vital Signs

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[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|------------------|---------------------|
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 0 Dec 2020 17:43:23 |
| User entered missing code ND - Not Done. | | 7 Aug 2020 16:16:23 |

US3292312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'bpm' | System | 31 Dec 2020 17:40:23 |
| User entered empty. | System | 30 Dec 2020 17:43:23 |
| User entered 'bpm' | System | 27 Aug 2020 16:16:23 |

US3292312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:07:18 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Kevin Martinez (b) (4) | 31 Dec 2020 17:40:23 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 30 Dec 2020 19:30:04 |
| Query 'Data is required. Please provide.' answered with 'N/A' (Site from System). | | 30 Dec 2020 17:43:43 |
| User opened query 'Data is required. Please provide.' System (Site from System). | | 30 Dec 2020 17:43:23 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 30 Dec 2020 17:43:23 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 27 Aug 2020 16:16:23 |

US3292312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'breaths/min' | System | 31 Dec 2020 17:40:23 |
| User entered empty. | System | 30 Dec 2020 17:43:23 |
| User entered 'breaths/min' | System | 27 Aug 2020 16:16:23 |

US3292312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:07:19 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Kevin Martinez (b) (4) | 31 Dec 2020 17:40:23 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 30 Dec 2020 19:30:01 |
| Query 'Data is required. Please provide.' answered with 'N/A' (Site from System). | | 30 Dec 2020 17:43:46 |
| User opened query 'Data is required. Please provide.' System (Site from System). | | 30 Dec 2020 17:43:23 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 30 Dec 2020 17:43:23 |
| User entered missing code ND - Not Done. | | 27 Aug 2020 16:16:23 |

US3292312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'mmHg' | System | 31 Dec 2020 17:40:23 |
| User entered empty. | System | 30 Dec 2020 17:43:23 |
| User entered 'mmHg' | System | 27 Aug 2020 16:16:23 |

US3292312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:07:21 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Kevin Martinez (b) (4) | 31 Dec 2020 17:40:23 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 30 Dec 2020 19:29:59 |
| Query 'Data is required. Please provide.' answered with 'N/A' (Site from System). | | 30 Dec 2020 17:43:49 |
| User opened query 'Data is required. Please provide.' System (Site from System). | | 30 Dec 2020 17:43:23 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 30 Dec 2020 17:43:23 |
| User entered missing code ND - Not Done. | | 27 Aug 2020 16:16:23 |

US3292312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'mmHg' | System | 31 Dec 2020 17:40:23 |
| User entered empty. | System | 30 Dec 2020 17:43:23 |
| User entered 'mmHg' | System | 27 Aug 2020 16:16:23 |

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |

US3292312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |

US3292312

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:30:59

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:07:31 |
| User entered 'Yes (Y)' | | 27 Aug 2020 16:16:31 |

US3292312

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:30:59

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:07:31 |
| User entered '25 Aug 2020' | (b) (4), (b) (6) | 27 Aug 2020 16:16:31 |

US3292312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:59

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 29 Jan 2021 15:10:20 |
| User entered 'No (N)' | | 27 Aug 2020 16:16:54 |

US3292312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:59

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:10:20 |
| User entered 'No (N)' | | 27 Aug 2020 16:16:54 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:59

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) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:10:20 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 16:16:54 |

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Folder: Screening

Form: Risk of Exposure

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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) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:10:20 |
| User entered 'No (N)' | | 7 Aug 2020 16:16:54 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:59

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:10:20 |
| User entered 'No (N)' | | 27 Aug 2020 16:16:54 |

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Folder: Screening

Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 29 Jan 2021 15:10:20 |
| User entered 'No (N)' | | 27 Aug 2020 16:16:54 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:59

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) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:10:20 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 16:16:54 |

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Folder: Screening

Form: Risk of Exposure

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[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 29 Jan 2021 15:10:20 |
| User entered 'No (N)' | | 27 Aug 2020 16:16:54 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:59

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) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:10:20 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 16:16:54 |

US3292312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:59

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) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 29 Jan 2021 15:10:20 |
| User entered 'No (N)' | | 27 Aug 2020 16:16:54 |

US3292312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:59

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) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 29 Jan 2021 15:10:20 |
| User entered 'No (N)' | | 27 Aug 2020 16:16:54 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:59

Other

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 29 Jan 2021 15:10:20 |
| User closed query 'Per CDM: As per CCG Page 25 Please indicate Yes or No.' (Site from DM). | | 29 Sep 2020 15:54:45 |
| Query 'Per CDM: As per CCG Page 25 Please indicate Yes or No.' answered with 'updated' (Site from DM). | Dawn Killian (b) (4) (b) (4) | 23 Sep 2020 18:47:59 |
| User entered 'No (N)' reason for change: Data Entry Error | Dawn Killian (b) (4) (b) (4) | 23 Sep 2020 18:47:51 |
| User opened query 'Per CDM: As per CCG Page 25 Please indicate Yes or No.' (Site from DM). | (b) (4), (b) (6) | 01 Sep 2020 16:05:59 |
| User closed query 'Data is required. Please complete.' (Site from System). | | 01 Sep 2020 14:09:29 |
| Query 'Data is required. Please complete.' answered with 'NA' (Site from System). | | 27 Aug 2020 16:16:58 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 27 Aug 2020 16:16:54 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:16:54 |

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:10:20 |
| User entered empty. | | 27 Aug 2020 16:16:54 |

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 16:16:54 |

US3292312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:59

Resides in Nursing Home or Assisted Living Facility

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 29 Jan 2021 15:10:20 |
| User entered '0' | | 27 Aug 2020 16:16:54 |

US3292312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:59

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) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 29 Jan 2021 15:10:20 |
| User entered '0' | | 27 Aug 2020 16:16:54 |

US3292312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:59

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) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:10:20 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 16:16:54 |

US3292312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:59

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) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 29 Jan 2021 15:10:20 |
| User entered '0' | | 27 Aug 2020 16:16:54 |

US3292312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:59

[Resides in a single family home \(i.e., detached housing\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:10:20 |
| User entered 'l' | | 27 Aug 2020 16:16:54 |

US3292312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:59

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 16:16:54 |

US3292312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:59

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:10:20 |
| User entered empty. | | 27 Aug 2020 16:16:54 |

US3292312

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:30:59

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:11:06 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 16:17:13 |

US3292312

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:11:06 |
| User entered '25 Aug 2020' | (b) (4), (b) (6) | 27 Aug 2020 16:17:13 |

US3292312

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:11:06 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 27 Aug 2020 16:17:13 |

US3292312

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:30:59

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered 'VISIT1' | System | 27 Aug 2020 16:17:13 |

US3292312

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 29 Jan 2021 15:12:17 |
| User entered '25 AUG 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 25 Aug 2020 19:34:49 |

US3292312

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:30:59

[What was the participant's randomization number?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 29 Jan 2021 15:12:19 |
| User entered '144718' | RWS_ENDPOINT ENDPOINT (b) (4) | 25 Aug 2020 19:34:49 |

US3292312

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:30:59

[In what Cohort was the participant enrolled?](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:06:59 |
| User closed query 'Please confirm with source' (Site from CRA). | (b) (4), (b) (6) | 16 Apr 2021 18:06:54 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| Query 'Please confirm with source' answered with 'correct as is?' (Site from CRA). | (b) (4) | |
| | Dawn Killian (b) (4) | 23 Mar 2021 18:53:47 |
| User opened query 'Please confirm with source' (Site from CRA). | (b) (4) | |
| | (b) (4), (b) (6) | 29 Jan 2021 15:12:45 |
| User entered '>=18 and <65 years and at risk (2)' | RWS_ENDPOINT ENDPOINT (b) (4) | 25 Aug 2020 19:34:49 |

US3292312

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:30:59

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) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:13:01 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 16:17:35 |

US3292312

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:30:59

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) | 25 Apr 2021 12:41:13 |
| DataPoint Verified. | | 16 Apr 2021 18:08:48 |
| User closed query 'Please confirm with source' (Site from CRA). | | 16 Apr 2021 18:08:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| Query 'Please confirm with source' answered with 'this is correct as is?' (Site from CRA). | (b) (4) | |
| | Dawn Killian (b) (4) | 23 Mar 2021 18:54:17 |
| User opened query 'Please confirm with source' (Site from CRA). | (b) (4) | |
| | (b) (4), (b) (6) | 29 Jan 2021 15:12:09 |
| User entered 'Yes (Y)' | | 27 Aug 2020 16:17:35 |

US3292312

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:30:59

Severe obesity (body mass index > or = 40kg/m2

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:13:03 |
| User entered 'No (N)' | | 27 Aug 2020 16:17:35 |

US3292312

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:30:59

Diabetes (Type I, Type 2, or gestational)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| DataPoint Verified. | | 16 Apr 2021 18:08:52 |
| User closed query 'Please confirm with source' (Site from CRA). | | 16 Apr 2021 18:08:51 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| Query 'Please confirm with source' answered with 'this is correct as is?' (Site from CRA). | (b) (4) | |
| | Dawn Killian (b) (4) | 23 Mar 2021 18:54:20 |
| User opened query 'Please confirm with source' (Site from CRA). | (b) (4) | |
| | (b) (4), (b) (6) | 29 Jan 2021 15:12:14 |
| User entered 'Yes (Y)' | | 7 Aug 2020 16:17:35 |

US3292312

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:30:59

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:13:05 |
| User entered 'No (N)' | | 27 Aug 2020 16:17:35 |

US3292312

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:30:59

Human Immunodeficiency Virus (HIV) infection

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:08:55 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 15:34:44 |
| Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'updated' (Site from DM). | Dawn Killian (b) (4) (b) (4) | 07 Dec 2020 23:17:42 |
| User entered 'No (N)' | Dawn Killian (b) (4) (b) (4) | 07 Dec 2020 23:17:39 |
| User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 01 Dec 2020 22:33:31 |
| Amendment Manager: DataPoint set to visible. | System | 19 Sep 2020 07:54:13 |
| Amendment Manager inserted this DataPoint. | System | 19 Sep 2020 07:54:12 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:30:59

[Height](#)

| Audit | User | Time (GMT) |
|--|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:13:30 |
| User entered missing code ND - Not Done. | | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:30:59

Weight

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:13:32 |
| User entered missing code ND - Not Done. | | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:30:59

[Height](#)

| Audit | User | Time (GMT) |
|--|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:13:30 |
| User entered missing code ND - Not Done. | | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:30:59

[Weight](#)

| Audit | User | Time (GMT) |
|--|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:13:32 |
| User entered missing code ND - Not Done. | | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User accepted default value 'Pre-Dose (PREDOSE)' | | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:14:21 |
| User entered 'Yes (Y)' | | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:14:21 |
| User entered '25 Aug 2020' | | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:14:21 |
| User entered '13:26' | (b) (4), (b) (6) | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered '25 Aug 2020 13:26' | System | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:14:21 |
| User entered '036.4' C | | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:14:21 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:14:21 |
| User entered empty. | | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:14:21 |
| User entered '057' | | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered 'bpm' | System | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:14:21 |
| User entered '020' | | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered 'breaths/min' | System | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 29 Jan 2021 15:14:21 |
| User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | System | 27 Aug 2020 16:19:22 |
| Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System). | System | 27 Aug 2020 16:19:22 |
| User entered '131' reason for change: Data Entry Error | (b) (4), (b) (6) | 27 Aug 2020 16:19:22 |
| User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | System | 27 Aug 2020 16:19:03 |
| User entered '13' | (b) (4), (b) (6) | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered 'mmHg' | System | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 29 Jan 2021 15:14:21 |
| User closed query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' (Site from System). | System | 27 Aug 2020 16:19:22 |
| Query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' answered by data change (Site from System). | System | 27 Aug 2020 16:19:22 |
| User opened query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' (Site from System). | System | 27 Aug 2020 16:19:03 |
| User entered '089' | (b) (4), (b) (6) | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered 'mmHg' | System | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:30:59

[Height](#)

| Audit | User | Time (GMT) |
|--|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:13:30 |
| User entered missing code ND - Not Done. | | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:30:59

[Weight](#)

| Audit | User | Time (GMT) |
|--|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:13:32 |
| User entered missing code ND - Not Done. | | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User accepted default value 'Post-Dose (POSTDOSE)' | | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:14:21 |
| User entered 'Yes (Y)' | | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:14:21 |
| User entered '25 Aug 2020' | | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:14:21 |
| User entered '15:20' | | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered '25 Aug 2020 15:20' | System | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:14:21 |
| User entered '36.7' C | | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:14:21 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:14:21 |
| User entered empty. | | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:14:21 |
| User entered '53' | | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered 'bpm' | System | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:14:21 |
| User entered '16' | | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered 'breaths/min' | System | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:14:21 |
| User entered '144' | | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered 'mmHg' | System | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:14:21 |
| User entered '82' | | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered 'mmHg' | System | 27 Aug 2020 16:19:03 |

US3292312

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:30:59

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:14:27 |
| User entered 'No (N)' | | 27 Aug 2020 16:19:29 |

US3292312

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:30:59

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:14:27 |
| User entered empty. | | 27 Aug 2020 16:19:29 |

US3292312

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:30:59

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:14:38 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Aug 2020 20:11:33 |

US3292312

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:30:59

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:14:38 |
| User entered empty. | (b) (4), (b) (6) | 25 Aug 2020 20:11:33 |

US3292312

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:14:38 |
| User entered empty. | | 25 Aug 2020 20:11:33 |

US3292312

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:30:59

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:30:59

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:14:38 |
| User entered '25 Aug 2020' | (b) (4), (b) (6) | 25 Aug 2020 20:11:33 |

US3292312

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:30:59

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:14:38 |
| User entered '14:45' | (b) (4), (b) (6) | 25 Aug 2020 20:11:33 |

US3292312

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:30:59

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered '25 Aug 2020 14:45' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:30:59

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:14:38 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4), (b) (6) | 25 Aug 2020 20:11:33 |

US3292312

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:30:59

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| DataPoint Verified. | | 29 Jan 2021 15:14:38 |
| User entered 'ONCE' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:30:59

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered 'INTRAMUSCULAR' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:30:59

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:14:57 |
| User entered 'Yes (Y)' | | 27 Aug 2020 16:19:42 |

US3292312

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:30:59

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:14:57 |
| User entered '25 Aug 2020' | (b) (4), (b) (6) | 27 Aug 2020 16:19:42 |

US3292312

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:30:59

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:14:57 |
| User entered '13:39' | | 27 Aug 2020 16:19:42 |

US3292312

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:30:59

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered '25 Aug 2020 13:39' | System | 27 Aug 2020 16:19:42 |

US3292312

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:30:59

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:17:19 |
| User entered '25 Aug 2020' | | 27 Aug 2020 16:19:55 |

US3292312

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:30:59

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | (b) (4), (b) (6) | 27 Aug 2020 16:19:55 |

US3292312

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:30:59

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:17:19 |
| User entered 'Yes (Y)' | | 27 Aug 2020 16:19:55 |

US3292312

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:30:59

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:17:19 |
| User entered '13:52' | | 27 Aug 2020 16:19:55 |

US3292312

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:30:59

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered '25 Aug 2020 13:52' | System | 27 Aug 2020 16:19:55 |

US3292312

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:30:59

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | | 27 Aug 2020 16:19:55 |

US3292312

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:30:59

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:17:19 |
| User entered 'No (N)' | | 27 Aug 2020 16:19:55 |

US3292312

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:30:59

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:17:19 |
| User entered empty. | | 27 Aug 2020 16:19:55 |

US3292312

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:30:59

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered empty. | System | 27 Aug 2020 16:19:55 |

US3292312

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 29 Jan 2021 15:17:25 |
| User entered 'Yes (Y)' | | 27 Aug 2020 16:19:59 |

US3292312

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered 'I' | System | 27 Aug 2020 16:19:59 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T15:26:09', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '586422c9-4945-4147-8c73-dbe3dbd3273b' User entered 'Yes (Y)' | System | 25 Aug 2020 20:26:39 |
| | System | 25 Aug 2020 20:26:39 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T15:26:20', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '586422c9-4945-4147-8c73-dbe3dbd3273b' User entered '98.0' | System | 25 Aug 2020 20:26:39 |
| | System | 25 Aug 2020 20:26:39 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T15:26:25', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '586422c9-4945-4147-8c73-dbe3dbd3273b' User entered 'No (N)' | System | 25 Aug 2020 20:26:39 |
| | System | 25 Aug 2020 20:26:39 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T15:26:36', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '586422c9-4945-4147-8c73-dbe3dbd3273b' User entered '25 Aug 2020 15:26' | System | 25 Aug 2020 20:26:39 |
| | System | 25 Aug 2020 20:26:39 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '25 Aug 2020 15:05' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '25 Aug 2020 17:35' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 1, after vaccination (at home)' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T21:36:50', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'b0bd83dc-61fb-4f83-94e2-8dece221ae22' | System | 26 Aug 2020 02:37:14 |
| User entered 'Yes (Y)' | System | 26 Aug 2020 02:37:14 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T21:36:58', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'b0bd83dc-61fb-4f83-94e2-8dece221ae22' User entered '97.9' | System | 26 Aug 2020 02:37:14 |
| | System | 26 Aug 2020 02:37:14 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T21:37:04', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'b0bd83dc-61fb-4f83-94e2-8dece221ae22' | System | 26 Aug 2020 02:37:14 |
| User entered 'No (N)' | System | 26 Aug 2020 02:37:14 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T21:37:11', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'b0bd83dc-61fb-4f83-94e2-8dece221ae22' | System | 26 Aug 2020 02:37:14 |
| User entered '25 Aug 2020 21:37' | System | 26 Aug 2020 02:37:14 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '25 Aug 2020 18:30' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '26 Aug 2020 11:59' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 2' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:30:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-26T14:57:42', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '6fcb402a-cdd8-45f3-b5cc-72a9e8cd1e0a' User entered 'Yes (Y)' | System | 26 Aug 2020 19:58:02 |
| | System | 26 Aug 2020 19:58:02 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:30:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-26T14:57:46', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '6fcb402a-cdd8-45f3-b5cc-72a9e8cd1e0a' User entered '97.1' | System | 26 Aug 2020 19:58:02 |
| | System | 26 Aug 2020 19:58:02 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-26T14:57:57', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '6fcb402a-cdd8-45f3-b5cc-72a9e8cd1e0a' | System | 26 Aug 2020 19:58:02 |
| User entered 'No (N)' | System | 26 Aug 2020 19:58:02 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-26T14:57:59', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '6fcb402a-cdd8-45f3-b5cc-72a9e8cd1e0a' User entered '26 Aug 2020 14:57' | System | 26 Aug 2020 19:58:02 |
| | System | 26 Aug 2020 19:58:02 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '26 Aug 2020 12:00' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '27 Aug 2020 11:59' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 3' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:30:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-27T15:10:07', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '60f87086-43d2-48a0-b8cc-c8b9fe54d409' User entered 'Yes (Y)' | System | 27 Aug 2020 20:10:27 |
| | System | 27 Aug 2020 20:10:27 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:30:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-27T15:10:12', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '60f87086-43d2-48a0-b8cc-c8b9fe54d409' User entered '97.4' | System | 27 Aug 2020 20:10:27 |
| | System | 27 Aug 2020 20:10:27 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-27T15:10:20', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '60f87086-43d2-48a0-b8cc-c8b9fe54d409' | System | 27 Aug 2020 20:10:27 |
| User entered 'No (N)' | System | 27 Aug 2020 20:10:27 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-27T15:10:24', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '60f87086-43d2-48a0-b8cc-c8b9fe54d409' | System | 27 Aug 2020 20:10:27 |
| User entered '27 Aug 2020 15:10' | System | 27 Aug 2020 20:10:27 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '27 Aug 2020 12:00' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '28 Aug 2020 11:59' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 4' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:30:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-28T22:08:28', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '08947a2b-d320-471f-827b-07f39eb05b77' | System | 29 Aug 2020 03:08:48 |
| User entered 'Yes (Y)' | System | 29 Aug 2020 03:08:48 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:30:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-28T22:08:34', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '08947a2b-d320-471f-827b-07f39eb05b77' User entered '97.4' | System | 29 Aug 2020 03:08:48 |
| | System | 29 Aug 2020 03:08:48 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-28T22:08:42', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '08947a2b-d320-471f-827b-07f39eb05b77' | System | 29 Aug 2020 03:08:48 |
| User entered 'No (N)' | System | 29 Aug 2020 03:08:48 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-28T22:08:45', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '08947a2b-d320-471f-827b-07f39eb05b77' | System | 29 Aug 2020 03:08:48 |
| User entered '28 Aug 2020 22:08' | System | 29 Aug 2020 03:08:48 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '28 Aug 2020 12:00' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '29 Aug 2020 11:59' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 5' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:30:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:30:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:30:59

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '29 Aug 2020 12:00' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '30 Aug 2020 11:59' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 6' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:30:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-30T21:56:27', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '9a12ac4c-2c74-4241-a03c-31ab5a74e231' User entered 'Yes (Y)' | System | 31 Aug 2020 02:57:39 |
| | System | 31 Aug 2020 02:57:39 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:30:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-30T21:57:29', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '9a12ac4c-2c74-4241-a03c-31ab5a74e231' User entered '97.5' | System | 31 Aug 2020 02:57:39 |
| | System | 31 Aug 2020 02:57:39 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-30T21:57:35', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '9a12ac4c-2c74-4241-a03c-31ab5a74e231' User entered 'No (N)' | System | 31 Aug 2020 02:57:39 |
| | System | 31 Aug 2020 02:57:39 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-30T21:57:38', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '9a12ac4c-2c74-4241-a03c-31ab5a74e231' User entered '30 Aug 2020 21:57' | System | 31 Aug 2020 02:57:39 |
| | System | 31 Aug 2020 02:57:39 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '30 Aug 2020 12:00' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '31 Aug 2020 11:59' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 7' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:30:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-31T20:57:12', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '14e15962-cd9c-45ec-ad55-100279d63f8f' User entered 'Yes (Y)' | System | 01 Sep 2020 01:57:35 |
| | System | 01 Sep 2020 01:57:35 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:30:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-31T20:57:23', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '14e15962-cd9c-45ec-ad55-100279d63f8f' User entered '97.5' | System | 01 Sep 2020 01:57:35 |
| | System | 01 Sep 2020 01:57:35 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-31T20:57:26', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '14e15962-cd9c-45ec-ad55-100279d63f8f' User entered 'No (N)' | System | 01 Sep 2020 01:57:35 |
| | System | 01 Sep 2020 01:57:35 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-31T20:57:33', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '14e15962-cd9c-45ec-ad55-100279d63f8f' User entered '31 Aug 2020 20:57' | System | 01 Sep 2020 01:57:35 |
| | System | 01 Sep 2020 01:57:35 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '31 Aug 2020 12:00' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '01 Sep 2020 11:59' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T15:26:55', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '91361c20-ec8e-4fe1-8d5b-5b83bf929587' | System | 25 Aug 2020 20:27:24 |
| User entered 'Does not interfere with activity (2)' | System | 25 Aug 2020 20:27:24 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T15:26:58', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '91361c20-ec8e-4fe1-8d5b-5b83bf929587' User entered 'No (N)' | System | 25 Aug 2020 20:27:24 |
| | System | 25 Aug 2020 20:27:24 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T15:27:01', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '91361c20-ec8e-4fe1-8d5b-5b83bf929587' User entered 'No (N)' | System | 25 Aug 2020 20:27:24 |
| | System | 25 Aug 2020 20:27:24 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T15:27:15', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '91361c20-ec8e-4fe1-8d5b-5b83bf929587' | System | 25 Aug 2020 20:27:24 |
| User entered 'None (1)' | System | 25 Aug 2020 20:27:24 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T15:27:19', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '91361c20-ec8e-4fe1-8d5b-5b83bf929587' User entered '25 Aug 2020 15:27' | System | 25 Aug 2020 20:27:24 |
| | System | 25 Aug 2020 20:27:24 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '25 Aug 2020 15:05' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '25 Aug 2020 17:35' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 1, after vaccination (at home)' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T21:37:24', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'b8229a6c-ee8b-4ceb-891d-4f77031b249b' | System | 26 Aug 2020 02:38:00 |
| User entered 'Does not interfere with activity (2)' | System | 26 Aug 2020 02:38:00 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T21:37:28', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'b8229a6c-ee8b-4ceb-891d-4f77031b249b' User entered 'No (N)' | System | 26 Aug 2020 02:38:00 |
| | System | 26 Aug 2020 02:38:00 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T21:37:46', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'b8229a6c-ee8b-4ceb-891d-4f77031b249b' User entered 'No (N)' | System | 26 Aug 2020 02:38:00 |
| | System | 26 Aug 2020 02:38:00 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T21:37:53', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'b8229a6c-ee8b-4ceb-891d-4f77031b249b' User entered 'None (1)' | System | 26 Aug 2020 02:38:00 |
| | System | 26 Aug 2020 02:38:00 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T21:37:56', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'b8229a6c-ee8b-4ceb-891d-4f77031b249b' User entered '25 Aug 2020 21:37' | System | 26 Aug 2020 02:38:00 |
| | System | 26 Aug 2020 02:38:00 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '25 Aug 2020 18:30' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '26 Aug 2020 11:59' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 2' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-26T14:58:20', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '27db9689-bce9-461d-96c5-3fb76fe788bd' | System | 26 Aug 2020 19:58:38 |
| User entered 'Does not interfere with activity (2)' | System | 26 Aug 2020 19:58:38 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:30:59

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-26T14:58:24', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '27db9689-bce9-461d-96c5-3fb76fe788bd' User entered 'No (N)' | System | 26 Aug 2020 19:58:38 |
| | System | 26 Aug 2020 19:58:38 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-26T14:58:28', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '27db9689-bce9-461d-96c5-3fb76fe788bd' | System | 26 Aug 2020 19:58:38 |
| User entered 'No (N)' | System | 26 Aug 2020 19:58:38 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-26T14:58:33', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '27db9689-bce9-461d-96c5-3fb76fe788bd' User entered 'None (1)' | System | 26 Aug 2020 19:58:38 |
| | System | 26 Aug 2020 19:58:38 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-26T14:58:35', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '27db9689-bce9-461d-96c5-3fb76fe788bd' User entered '26 Aug 2020 14:58' | System | 26 Aug 2020 19:58:38 |
| | System | 26 Aug 2020 19:58:38 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '26 Aug 2020 12:00' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '27 Aug 2020 11:59' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 3' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-27T15:10:38', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '28c537f8-4873-40f0-854c-69968ff865ca' User entered 'Does not interfere with activity (2)' | System | 27 Aug 2020 20:11:06 |
| | System | 27 Aug 2020 20:11:06 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:30:59

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-27T15:10:41', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '28c537f8-4873-40f0-854c-69968ff865ca' | System | 27 Aug 2020 20:11:06 |
| User entered 'No (N)' | System | 27 Aug 2020 20:11:06 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-27T15:10:44', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '28c537f8-4873-40f0-854c-69968ff865ca' | System | 27 Aug 2020 20:11:06 |
| User entered 'No (N)' | System | 27 Aug 2020 20:11:06 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-27T15:10:55', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '28c537f8-4873-40f0-854c-69968ff865ca' | System | 27 Aug 2020 20:11:06 |
| User entered 'None (1)' | System | 27 Aug 2020 20:11:06 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-27T15:11:01', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '28c537f8-4873-40f0-854c-69968ff865ca' User entered '27 Aug 2020 15:11' | System | 27 Aug 2020 20:11:06 |
| | System | 27 Aug 2020 20:11:06 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '27 Aug 2020 12:00' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '28 Aug 2020 11:59' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 4' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-28T22:08:54', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '5f8a78ba-aaf5-4da7-91f7-c9b1adc342b4' | System | 29 Aug 2020 03:09:09 |
| User entered 'None (1)' | System | 29 Aug 2020 03:09:09 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:30:59

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-28T22:08:57', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '5f8a78ba-aaf5-4da7-91f7-c9b1ade342b4' User entered 'No (N)' | System | 29 Aug 2020 03:09:09 |
| | System | 29 Aug 2020 03:09:09 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-28T22:09:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '5f8a78ba-aaf5-4da7-91f7-c9b1ade342b4' User entered 'No (N)' | System | 29 Aug 2020 03:09:09 |
| | System | 29 Aug 2020 03:09:09 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-28T22:09:05', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '5f8a78ba-aaf5-4da7-91f7-c9b1adc342b4' User entered 'None (1)' | System | 29 Aug 2020 03:09:09 |
| | System | 29 Aug 2020 03:09:09 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-28T22:09:08', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '5f8a78ba-aaf5-4da7-91f7-c9b1ade342b4' User entered '28 Aug 2020 22:09' | System | 29 Aug 2020 03:09:09 |
| | System | 29 Aug 2020 03:09:09 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '28 Aug 2020 12:00' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '29 Aug 2020 11:59' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 5' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:30:59

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:30:59

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) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:30:59

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) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '29 Aug 2020 12:00' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '30 Aug 2020 11:59' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 6' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-30T21:57:48', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'd5ac2065-73ce-4fff-942b-84247dfca14a' | System | 31 Aug 2020 02:58:12 |
| User entered 'None (1)' | System | 31 Aug 2020 02:58:12 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:30:59

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-30T21:57:51', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'd5ac2065-73ce-4fff-942b-84247dfca14a' | System | 31 Aug 2020 02:58:12 |
| User entered 'No (N)' | System | 31 Aug 2020 02:58:12 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-30T21:58:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'd5ac2065-73ce-4fff-942b-84247dfca14a' User entered 'No (N)' | System | 31 Aug 2020 02:58:12 |
| | System | 31 Aug 2020 02:58:12 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-30T21:58:04', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'd5ac2065-73ce-4fff-942b-84247dfca14a' | System | 31 Aug 2020 02:58:12 |
| User entered 'None (1)' | System | 31 Aug 2020 02:58:12 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-30T21:58:10', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'd5ac2065-73ce-4fff-942b-84247dfca14a' User entered '30 Aug 2020 21:58' | System | 31 Aug 2020 02:58:12 |
| | System | 31 Aug 2020 02:58:12 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '30 Aug 2020 12:00' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '31 Aug 2020 11:59' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 7' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-31T20:57:36', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'e228de8d-a3c8-4b74-b3d9-90d918c63456' | System | 01 Sep 2020 01:57:55 |
| User entered 'None (1)' | System | 01 Sep 2020 01:57:55 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:30:59

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-31T20:57:39', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'e228de8d-a3c8-4b74-b3d9-90d918c63456' User entered 'No (N)' | System | 01 Sep 2020 01:57:55 |
| | System | 01 Sep 2020 01:57:55 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-31T20:57:41', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'e228de8d-a3c8-4b74-b3d9-90d918c63456' User entered 'No (N)' | System | 01 Sep 2020 01:57:55 |
| | System | 01 Sep 2020 01:57:55 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-31T20:57:49', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'e228de8d-a3c8-4b74-b3d9-90d918c63456' | System | 01 Sep 2020 01:57:55 |
| User entered 'None (1)' | System | 01 Sep 2020 01:57:55 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-31T20:57:52', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'e228de8d-a3c8-4b74-b3d9-90d918c63456' User entered '31 Aug 2020 20:57' | System | 01 Sep 2020 01:57:55 |
| | System | 01 Sep 2020 01:57:55 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '31 Aug 2020 12:00' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '01 Sep 2020 11:59' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T15:27:27', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'a1a3ab04-3405-476c-8223-a22f1656310e' | System | 25 Aug 2020 20:27:55 |
| User entered 'No interference with activity (1)' | System | 25 Aug 2020 20:27:55 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T15:27:31', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'a1a3ab04-3405-476c-8223-a22f1656310e' User entered 'None (0)' | System | 25 Aug 2020 20:27:55 |
| | System | 25 Aug 2020 20:27:55 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T15:27:37', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'a1a3ab04-3405-476c-8223-a22f1656310e' User entered 'None (0)' | System | 25 Aug 2020 20:27:55 |
| | System | 25 Aug 2020 20:27:55 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T15:27:40', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'a1a3ab04-3405-476c-8223-a22f1656310e' User entered 'None (0)' | System | 25 Aug 2020 20:27:55 |
| | System | 25 Aug 2020 20:27:55 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T15:27:42', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'a1a3ab04-3405-476c-8223-a22f1656310e' User entered 'None (0)' | System | 25 Aug 2020 20:27:55 |
| | System | 25 Aug 2020 20:27:55 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T15:27:45', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'a1a3ab04-3405-476c-8223-a22f1656310e' User entered 'None (0)' | System | 25 Aug 2020 20:27:55 |
| | System | 25 Aug 2020 20:27:55 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T15:27:51', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'a1a3ab04-3405-476c-8223-a22f1656310e' User entered 'No (N)' | System | 25 Aug 2020 20:27:55 |
| | System | 25 Aug 2020 20:27:55 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T15:27:53', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'a1a3ab04-3405-476c-8223-a22f1656310e' User entered '25 Aug 2020 15:27' | System | 25 Aug 2020 20:27:55 |
| | System | 25 Aug 2020 20:27:55 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '25 Aug 2020 15:05' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '25 Aug 2020 17:35' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 1, after vaccination (at home)' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T21:38:03', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '6c288294-8b0e-4d10-a687-550414cbdb2f' User entered 'None (0)' | System | 26 Aug 2020 02:38:41 |
| | System | 26 Aug 2020 02:38:41 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T21:38:13', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '6c288294-8b0e-4d10-a687-550414cbdb2f' User entered 'None (0)' | System | 26 Aug 2020 02:38:41 |
| | System | 26 Aug 2020 02:38:41 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T21:38:16', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '6c288294-8b0e-4d10-a687-550414cbdb2f' User entered 'None (0)' | System | 26 Aug 2020 02:38:41 |
| | System | 26 Aug 2020 02:38:41 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T21:38:18', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '6c288294-8b0e-4d10-a687-550414cbdb2f' User entered 'None (0)' | System | 26 Aug 2020 02:38:41 |
| | System | 26 Aug 2020 02:38:41 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T21:38:21', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '6c288294-8b0e-4d10-a687-550414cbdb2f' User entered 'None (0)' | System | 26 Aug 2020 02:38:41 |
| | System | 26 Aug 2020 02:38:41 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T21:38:23', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '6c288294-8b0e-4d10-a687-550414cbdb2f' User entered 'None (0)' | System | 26 Aug 2020 02:38:41 |
| | System | 26 Aug 2020 02:38:41 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T21:38:32', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '6c288294-8b0e-4d10-a687-550414cbdb2f' User entered 'No (N)' | System | 26 Aug 2020 02:38:41 |
| | System | 26 Aug 2020 02:38:41 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-25T21:38:39', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '6c288294-8b0e-4d10-a687-550414cbdb2f' User entered '25 Aug 2020 21:38' | System | 26 Aug 2020 02:38:41 |
| | System | 26 Aug 2020 02:38:41 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '25 Aug 2020 18:30' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '26 Aug 2020 11:59' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 2' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-26T14:58:43', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '09a6b92c-ba9f-4745-bb02-527d54d54ea1' User entered 'None (0)' | System | 26 Aug 2020 19:59:09 |
| | System | 26 Aug 2020 19:59:09 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-26T14:58:48', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '09a6b92c-ba9f-4745-bb02-527d54d54ea1' User entered 'None (0)' | System | 26 Aug 2020 19:59:09 |
| | System | 26 Aug 2020 19:59:09 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-26T14:58:51', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '09a6b92c-ba9f-4745-bb02-527d54d54ea1' User entered 'None (0)' | System | 26 Aug 2020 19:59:09 |
| | System | 26 Aug 2020 19:59:09 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-26T14:58:53', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '09a6b92c-ba9f-4745-bb02-527d54d54ea1' User entered 'None (0)' | System | 26 Aug 2020 19:59:09 |
| | System | 26 Aug 2020 19:59:09 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-26T14:58:54', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '09a6b92c-ba9f-4745-bb02-527d54d54ea1' User entered 'None (0)' | System | 26 Aug 2020 19:59:09 |
| | System | 26 Aug 2020 19:59:09 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-26T14:58:56', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '09a6b92c-ba9f-4745-bb02-527d54d54ea1' User entered 'None (0)' | System | 26 Aug 2020 19:59:09 |
| | System | 26 Aug 2020 19:59:09 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-26T14:59:02', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '09a6b92c-ba9f-4745-bb02-527d54d54ea1' User entered 'No (N)' | System | 26 Aug 2020 19:59:09 |
| | System | 26 Aug 2020 19:59:09 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-26T14:59:05', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '09a6b92c-ba9f-4745-bb02-527d54d54ea1' User entered '26 Aug 2020 14:59' | System | 26 Aug 2020 19:59:09 |
| | System | 26 Aug 2020 19:59:09 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '26 Aug 2020 12:00' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '27 Aug 2020 11:59' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 3' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-27T15:11:16', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '2dc88438-4540-44a3-9e5e-98358368bd30' | System | 27 Aug 2020 20:12:08 |
| User entered 'None (0)' | System | 27 Aug 2020 20:12:08 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-27T15:11:34', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '2dc88438-4540-44a3-9e5e-98358368bd30' User entered 'None (0)' | System | 27 Aug 2020 20:12:08 |
| | System | 27 Aug 2020 20:12:08 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-27T15:11:38', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '2dc88438-4540-44a3-9e5e-98358368bd30' | System | 27 Aug 2020 20:12:08 |
| User entered 'None (0)' | System | 27 Aug 2020 20:12:08 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-27T15:11:40', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '2dc88438-4540-44a3-9e5e-98358368bd30' User entered 'None (0)' | System | 27 Aug 2020 20:12:08 |
| | System | 27 Aug 2020 20:12:08 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-27T15:11:43', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '2dc88438-4540-44a3-9e5e-98358368bd30' User entered 'None (0)' | System | 27 Aug 2020 20:12:08 |
| | System | 27 Aug 2020 20:12:08 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-27T15:11:46', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '2dc88438-4540-44a3-9e5e-98358368bd30' User entered 'None (0)' | System | 27 Aug 2020 20:12:08 |
| | System | 27 Aug 2020 20:12:08 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-27T15:12:01', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '2dc88438-4540-44a3-9e5e-98358368bd30' | System | 27 Aug 2020 20:12:08 |
| User entered 'No (N)' | System | 27 Aug 2020 20:12:08 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-27T15:12:04', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '2dc88438-4540-44a3-9e5e-98358368bd30' | System | 27 Aug 2020 20:12:08 |
| User entered '27 Aug 2020 15:12' | System | 27 Aug 2020 20:12:08 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '27 Aug 2020 12:00' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '28 Aug 2020 11:59' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 4' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-28T22:09:13', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'd8387a53-9121-4133-b412-cdb08aa60a27' User entered 'None (0)' | System | 29 Aug 2020 03:09:37 |
| | System | 29 Aug 2020 03:09:37 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-28T22:09:15', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'd8387a53-9121-4133-b412-cdb08aa60a27' | System | 29 Aug 2020 03:09:37 |
| User entered 'None (0)' | System | 29 Aug 2020 03:09:37 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-28T22:09:16', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'd8387a53-9121-4133-b412-cdb08aa60a27' User entered 'None (0)' | System | 29 Aug 2020 03:09:37 |
| | System | 29 Aug 2020 03:09:37 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-28T22:09:18', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'd8387a53-9121-4133-b412-cdb08aa60a27' User entered 'None (0)' | System | 29 Aug 2020 03:09:37 |
| | System | 29 Aug 2020 03:09:37 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-28T22:09:20', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'd8387a53-9121-4133-b412-cdb08aa60a27' User entered 'None (0)' | System | 29 Aug 2020 03:09:37 |
| | System | 29 Aug 2020 03:09:37 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-28T22:09:22', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'd8387a53-9121-4133-b412-cdb08aa60a27' User entered 'None (0)' | System | 29 Aug 2020 03:09:37 |
| | System | 29 Aug 2020 03:09:37 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-28T22:09:28', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'd8387a53-9121-4133-b412-cdb08aa60a27' | System | 29 Aug 2020 03:09:37 |
| User entered 'No (N)' | System | 29 Aug 2020 03:09:37 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-28T22:09:31', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'd8387a53-9121-4133-b412-cdb08aa60a27' | System | 29 Aug 2020 03:09:37 |
| User entered '28 Aug 2020 22:09' | System | 29 Aug 2020 03:09:37 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '28 Aug 2020 12:00' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '29 Aug 2020 11:59' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 5' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:30:59

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:30:59

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:30:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:30:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:30:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:30:59

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:30:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '29 Aug 2020 12:00' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '30 Aug 2020 11:59' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 6' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-30T21:58:13', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '451bcb47-e69f-45ab-b066-d7d843fc7628' User entered 'None (0)' | System | 31 Aug 2020 02:58:40 |
| | System | 31 Aug 2020 02:58:40 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-30T21:58:15', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '451bcb47-e69f-45ab-b066-d7d843fc7628' User entered 'None (0)' | System | 31 Aug 2020 02:58:40 |
| | System | 31 Aug 2020 02:58:40 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-30T21:58:17', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '451bcb47-e69f-45ab-b066-d7d843fc7628' User entered 'None (0)' | System | 31 Aug 2020 02:58:40 |
| | System | 31 Aug 2020 02:58:40 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-30T21:58:19', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '451bcb47-e69f-45ab-b066-d7d843fc7628' User entered 'None (0)' | System | 31 Aug 2020 02:58:40 |
| | System | 31 Aug 2020 02:58:40 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-30T21:58:21', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '451bcb47-e69f-45ab-b066-d7d843fc7628' User entered 'None (0)' | System | 31 Aug 2020 02:58:40 |
| | System | 31 Aug 2020 02:58:40 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-30T21:58:24', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '451bcb47-e69f-45ab-b066-d7d843fc7628' User entered 'None (0)' | System | 31 Aug 2020 02:58:40 |
| | System | 31 Aug 2020 02:58:40 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-30T21:58:29', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '451bcb47-e69f-45ab-b066-d7d843fc7628' User entered 'No (N)' | System | 31 Aug 2020 02:58:40 |
| | System | 31 Aug 2020 02:58:40 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-30T21:58:35', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '451bcb47-e69f-45ab-b066-d7d843fc7628' User entered '30 Aug 2020 21:58' | System | 31 Aug 2020 02:58:40 |
| | System | 31 Aug 2020 02:58:40 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '30 Aug 2020 12:00' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '31 Aug 2020 11:59' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 7' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-31T20:57:55', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '055a2ccb-997e-45ae-883b-127c769b764f' User entered 'None (0)' | System | 01 Sep 2020 01:58:22 |
| | System | 01 Sep 2020 01:58:22 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-31T20:57:58', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '055a2ccb-997e-45ae-883b-127c769b764f' User entered 'None (0)' | System | 01 Sep 2020 01:58:22 |
| | System | 01 Sep 2020 01:58:22 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-31T20:58:02', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '055a2ccb-997e-45ae-883b-127c769b764f' User entered 'None (0)' | System | 01 Sep 2020 01:58:22 |
| | System | 01 Sep 2020 01:58:22 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-31T20:58:06', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '055a2ccb-997e-45ae-883b-127c769b764f' User entered 'None (0)' | System | 01 Sep 2020 01:58:22 |
| | System | 01 Sep 2020 01:58:22 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-31T20:58:08', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '055a2ccb-997e-45ae-883b-127c769b764f' User entered 'None (0)' | System | 01 Sep 2020 01:58:22 |
| | System | 01 Sep 2020 01:58:22 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-31T20:58:10', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '055a2ccb-997e-45ae-883b-127c769b764f' User entered 'None (0)' | System | 01 Sep 2020 01:58:22 |
| | System | 01 Sep 2020 01:58:22 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-31T20:58:15', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '055a2ccb-997e-45ae-883b-127c769b764f' User entered 'No (N)' | System | 01 Sep 2020 01:58:22 |
| | System | 01 Sep 2020 01:58:22 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-08-31T20:58:17', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '055a2ccb-997e-45ae-883b-127c769b764f' User entered '31 Aug 2020 20:58' | System | 01 Sep 2020 01:58:22 |
| | System | 01 Sep 2020 01:58:22 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '31 Aug 2020 12:00' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '01 Sep 2020 11:59' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:24:21 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) | 02 Sep 2020 19:31:06 |

US3292312

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:24:21 |
| User entered '02 Sep 2020' reason for change: New Information | Antonio Gutierrez (b) (4) | 10 Nov 2020 15:42:08 |
| User entered '2 Sep 2020' | Kristy Trevino (b) (4) | 02 Sep 2020 19:31:06 |

US3292312

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:24:21 |
| User entered 'Contact Made (CONTACT MADE)' | Kristy Trevino (b) (4) | 02 Sep 2020 19:31:06 |

US3292312

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:24:21 |
| User entered empty. | Kristy Trevino (b) (4) | 02 Sep 2020 19:31:06 |

US3292312

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:24:24 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) | 02 Sep 2020 19:33:57 |

US3292312

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered 'l' | System | 02 Sep 2020 19:33:57 |

US3292312

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:25:32 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) | 09 Sep 2020 23:30:53 |

US3292312

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 29 Jan 2021 14:25:32 |
| User entered '09 Sep 2020' reason for change: New Information | Antonio Gutierrez (b) (4) | 10 Nov 2020 15:30:00 |
| User entered '9 Sep 2020' | Kristy Trevino (b) (4) (b) (4) | 09 Sep 2020 23:30:53 |

US3292312

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:25:32 |
| User entered 'Contact Made (CONTACT MADE)' | Kristy Trevino (b) (4) | 09 Sep 2020 23:30:53 |

US3292312

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:25:32 |
| User entered empty. | Kristy Trevino (b) (4) | 09 Sep 2020 23:30:53 |

US3292312

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:25:36 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) | 09 Sep 2020 23:30:57 |

US3292312

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered 'l' | System | 09 Sep 2020 23:30:57 |

US3292312

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:26:25 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) | 16 Sep 2020 20:12:47 |

US3292312

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:26:25 |
| User entered '16 Sep 2020' | Kristy Trevino (b) (4) | 16 Sep 2020 20:12:47 |

US3292312

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:26:25 |
| User entered 'Contact Made (CONTACT MADE)' | Kristy Trevino (b) (4) | 16 Sep 2020 20:12:47 |

US3292312

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:26:25 |
| User entered empty. | Kristy Trevino (b) (4) | 16 Sep 2020 20:12:47 |

US3292312

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:26:43 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) | 16 Sep 2020 20:12:53 |

US3292312

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered 'I' | System | 16 Sep 2020 20:12:53 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:30:59

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:17:44 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 20:30:10 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 29 Jan 2021 15:17:44 |
| User entered '22 Sep 2020' | | 22 Sep 2020 20:30:10 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:17:44 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 22 Sep 2020 20:30:10 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:30:59

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User entered 'VISIT2' | System | 22 Sep 2020 20:30:10 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User accepted default value 'Pre-Dose (PREDOSE)' | | 22 Sep 2020 20:33:15 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 29 Jan 2021 15:19:25 |
| User entered 'Yes (Y)' | | 22 Sep 2020 20:33:15 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:19:27 |
| User entered '22 Sep 2020' | | 22 Sep 2020 20:33:15 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:19:29 |
| User entered '13:55' | | 22 Sep 2020 20:33:15 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User entered '22 Sep 2020 13:55' | System | 22 Sep 2020 20:33:15 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User closed query 'Please confirm with source' (Site from CRA). | | 16 Apr 2021 18:14:44 |
| DataPoint Verified. | | 16 Apr 2021 18:14:42 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| Query 'Please confirm with source' answered with 'correct as is' (Site from CRA). | (b) (4) | |
| | Dawn Killian (b) (4) | 23 Mar 2021 18:52:59 |
| User opened query 'Please confirm with source' (Site from CRA). | (b) (4) | |
| | (b) (4), (b) (6) | 29 Jan 2021 15:19:45 |
| User entered '37.0' C | | 22 Sep 2020 20:33:15 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:19:30 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 22 Sep 2020 20:33:15 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:19:33 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 20:33:15 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:19:47 |
| User entered '67' | (b) (4), (b) (6) | 22 Sep 2020 20:33:15 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User entered 'bpm' | System | 22 Sep 2020 20:33:15 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:19:48 |
| User entered '20' | (b) (4), (b) (6) | 22 Sep 2020 20:33:15 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User entered 'breaths/min' | System | 22 Sep 2020 20:33:15 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:19:50 |
| User entered '94' | | 22 Sep 2020 20:33:15 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User entered 'mmHg' | System | 22 Sep 2020 20:33:15 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:19:51 |
| User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | (b) (4), (b) (6) | 16 Oct 2020 15:12:04 |
| Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per pi' (Site from System). | | 22 Sep 2020 20:34:03 |
| User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | | 22 Sep 2020 20:33:15 |
| User entered '59' | (b) (4), (b) (6) | 22 Sep 2020 20:33:15 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:59

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User entered 'mmHg' | System | 22 Sep 2020 20:33:15 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User accepted default value 'Post-Dose (POSTDOSE)' | | 22 Sep 2020 20:35:02 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:20:16 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 20:35:02 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:20:18 |
| User entered '22 Sep 2020' | (b) (4), (b) (6) | 22 Sep 2020 20:35:02 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:20:20 |
| User entered '15:15' | | 22 Sep 2020 20:35:02 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User entered '22 Sep 2020 15:15' | System | 22 Sep 2020 20:35:02 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:20:22 |
| User entered '36.8' C | | 22 Sep 2020 20:35:02 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:20:24 |
| User entered 'Oral (Oral)' | | 22 Sep 2020 20:35:02 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 29 Jan 2021 15:20:25 |
| User entered empty. | | 22 Sep 2020 20:35:02 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:20:27 |
| User entered '66' | | 22 Sep 2020 20:35:02 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User entered 'bpm' | System | 22 Sep 2020 20:35:02 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:20:29 |
| User entered '16' | (b) (4), (b) (6) | 22 Sep 2020 20:35:02 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User entered 'breaths/min' | System | 22 Sep 2020 20:35:02 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:20:31 |
| User entered '103' | (b) (4), (b) (6) | 22 Sep 2020 20:35:02 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User entered 'mmHg' | System | 22 Sep 2020 20:35:02 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:20:32 |
| User entered '69' | (b) (4), (b) (6) | 22 Sep 2020 20:35:02 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:59

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User entered 'mmHg' | System | 22 Sep 2020 20:35:02 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:30:59

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:22:32 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 20:35:09 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:30:59

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:22:32 |
| User entered '22 Sep 2020' | | 22 Sep 2020 20:35:09 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:30:59

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:24:07 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 22 Sep 2020 19:55:17 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:30:59

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:24:07 |
| User entered empty. | Nathan Cortez (b) (4) | 22 Sep 2020 19:55:17 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:24:07 |
| User entered empty. | Nathan Cortez (b) (4) | 22 Sep 2020 19:55:17 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:30:59

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:30:59

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:24:07 |
| User entered '22 Sep 2020' | Nathan Cortez (b) (4) | 22 Sep 2020 19:55:17 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:30:59

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:24:07 |
| User entered '14:45' | Nathan Cortez (b) (4) | 22 Sep 2020 19:55:17 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:30:59

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User entered '22 Sep 2020 14:45' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:30:59

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:24:07 |
| User entered 'Left Arm (LEFT ARM)' | Nathan Cortez (b) (4) | 22 Sep 2020 19:55:17 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:30:59

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| DataPoint Verified. | | 29 Jan 2021 15:24:07 |
| User entered 'ONCE' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:30:59

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User entered 'INTRAMUSCULAR' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:30:59

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 29 Jan 2021 15:25:12 |
| User entered 'Yes (Y)' | | 22 Sep 2020 20:35:35 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:30:59

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 29 Jan 2021 15:25:12 |
| User entered '22 Sep 2020' | | 22 Sep 2020 20:35:35 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:30:59

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:25:12 |
| User entered '14:05' | (b) (4), (b) (6) | 22 Sep 2020 20:35:35 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:30:59

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User entered '22 Sep 2020 14:05' | System | 22 Sep 2020 20:35:35 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:30:59

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 15:25:18 |
| User entered '22 Sep 2020' | | 22 Sep 2020 20:36:01 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:30:59

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | (b) (4), (b) (6) | 22 Sep 2020 20:36:01 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:30:59

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:25:18 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 20:36:01 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:30:59

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:25:18 |
| User entered '14:13' | (b) (4), (b) (6) | 22 Sep 2020 20:36:01 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:30:59

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered '22 Sep 2020 14:13' | System | 22 Sep 2020 20:36:01 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:30:59

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | (b) (4), (b) (6) | 22 Sep 2020 20:36:01 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:30:59

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:25:18 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 20:36:01 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:30:59

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 15:25:18 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 20:36:01 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:30:59

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered empty. | System | 22 Sep 2020 20:36:01 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 29 Jan 2021 15:25:31 |
| User entered 'Yes (Y)' | | 22 Sep 2020 20:36:18 |

US3292312

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered 'I' | System | 22 Sep 2020 20:36:18 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 22 Sep 2020 19:55:17 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T15:18:07', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'c69ecedb-b3e7-470b-b596-49914cf8be40' | System | 22 Sep 2020 20:18:34 |
| User entered 'Yes (Y)' | System | 22 Sep 2020 20:18:34 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T15:18:15', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'c69ecedb-b3e7-470b-b596-49914cf8be40' User entered '98.2' | System | 22 Sep 2020 20:18:34 |
| | System | 22 Sep 2020 20:18:34 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T15:18:26', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'c69ecedb-b3e7-470b-b596-49914cf8be40' | System | 22 Sep 2020 20:18:34 |
| User entered 'No (N)' | System | 22 Sep 2020 20:18:34 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T15:18:31', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'c69ecedb-b3e7-470b-b596-49914cf8be40' User entered '22 Sep 2020 15:18' | System | 22 Sep 2020 20:18:34 |
| | System | 22 Sep 2020 20:18:34 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '22 Sep 2020 15:05' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '22 Sep 2020 17:35' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 22 Sep 2020 19:55:17 |
| User entered 'Day 1, after vaccination (at home)' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T21:16:04', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '859fca1b-e662-4b66-914e-8e194c4b9f30' User entered 'Yes (Y)' | System | 23 Sep 2020 02:16:37 |
| | System | 23 Sep 2020 02:16:37 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T21:16:22', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '859fca1b-e662-4b66-914e-8e194c4b9f30' User entered '97.8' | System | 23 Sep 2020 02:16:37 |
| | System | 23 Sep 2020 02:16:37 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T21:16:26', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '859fca1b-e662-4b66-914e-8e194c4b9f30' | System | 23 Sep 2020 02:16:37 |
| User entered 'No (N)' | System | 23 Sep 2020 02:16:37 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T21:16:31', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '859fca1b-e662-4b66-914e-8e194c4b9f30' | System | 23 Sep 2020 02:16:37 |
| User entered '22 Sep 2020 21:16' | System | 23 Sep 2020 02:16:37 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '22 Sep 2020 18:30' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '23 Sep 2020 11:59' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 22 Sep 2020 19:55:17 |
| User entered 'Day 2' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:30:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-23T20:41:12', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'b85d29f3-c5a9-4a72-887c-3ea40b145075' | System | 24 Sep 2020 01:41:33 |
| User entered 'Yes (Y)' | System | 24 Sep 2020 01:41:33 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:30:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-23T20:41:20', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'b85d29f3-c5a9-4a72-887c-3ea40b145075' User entered '98.5' | System | 24 Sep 2020 01:41:33 |
| | System | 24 Sep 2020 01:41:33 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-23T20:41:25', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'b85d29f3-c5a9-4a72-887c-3ea40b145075' User entered 'No (N)' | System | 24 Sep 2020 01:41:33 |
| | System | 24 Sep 2020 01:41:33 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-23T20:41:31', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'b85d29f3-c5a9-4a72-887c-3ea40b145075' User entered '23 Sep 2020 20:41' | System | 24 Sep 2020 01:41:33 |
| | System | 24 Sep 2020 01:41:33 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '23 Sep 2020 12:00' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '24 Sep 2020 11:59' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 22 Sep 2020 19:55:17 |
| User entered 'Day 3' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:30:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-24T20:42:18', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'd548626b-9ad3-4fd1-a259-229e940c3eed' User entered 'Yes (Y)' | System | 25 Sep 2020 01:42:34 |
| | System | 25 Sep 2020 01:42:34 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:30:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-24T20:42:23', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'd548626b-9ad3-4fd1-a259-229e940c3eed' User entered '97.1' | System | 25 Sep 2020 01:42:34 |
| | System | 25 Sep 2020 01:42:34 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-24T20:42:26', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'd548626b-9ad3-4fd1-a259-229e940c3eed' User entered 'No (N)' | System | 25 Sep 2020 01:42:34 |
| | System | 25 Sep 2020 01:42:34 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-24T20:42:32', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'd548626b-9ad3-4fd1-a259-229e940c3eed' User entered '24 Sep 2020 20:42' | System | 25 Sep 2020 01:42:34 |
| | System | 25 Sep 2020 01:42:34 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '24 Sep 2020 12:00' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '25 Sep 2020 11:59' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 22 Sep 2020 19:55:17 |
| User entered 'Day 4' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:30:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-25T20:25:04', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'e71be283-afb5-4e88-a781-10c4d0778fac' User entered 'Yes (Y)' | System | 26 Sep 2020 01:25:33 |
| | System | 26 Sep 2020 01:25:33 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:30:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-25T20:25:12', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'e71be283-afb5-4e88-a781-10c4d0778fac' User entered '97.3' | System | 26 Sep 2020 01:25:33 |
| | System | 26 Sep 2020 01:25:33 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-25T20:25:19', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'e71be283-afb5-4e88-a781-10c4d0778fac' | System | 26 Sep 2020 01:25:33 |
| User entered 'No (N)' | System | 26 Sep 2020 01:25:33 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-25T20:25:27', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'e71be283-afb5-4e88-a781-10c4d0778fac' | System | 26 Sep 2020 01:25:33 |
| User entered '25 Sep 2020 20:25' | System | 26 Sep 2020 01:25:33 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '25 Sep 2020 12:00' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '26 Sep 2020 11:59' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 22 Sep 2020 19:55:17 |
| User entered 'Day 5' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:30:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:30:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:30:59

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '26 Sep 2020 12:00' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '27 Sep 2020 11:59' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 22 Sep 2020 19:55:17 |
| User entered 'Day 6' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:30:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T06:41:07', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'baeea939-507a-4d1d-9f97-ea145623e822' | System | 28 Sep 2020 11:41:28 |
| User entered 'Yes (Y)' | System | 28 Sep 2020 11:41:28 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:30:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T06:41:17', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'baeea939-507a-4d1d-9f97-ea145623e822' User entered '96.9' | System | 28 Sep 2020 11:41:28 |
| | System | 28 Sep 2020 11:41:28 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T06:41:23', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'baeea939-507a-4d1d-9f97-ea145623e822' | System | 28 Sep 2020 11:41:28 |
| User entered 'No (N)' | System | 28 Sep 2020 11:41:28 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T06:41:26', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'baeea939-507a-4d1d-9f97-ea145623e822' | System | 28 Sep 2020 11:41:28 |
| User entered '28 Sep 2020 06:41' | System | 28 Sep 2020 11:41:28 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '27 Sep 2020 12:00' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '28 Sep 2020 11:59' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 22 Sep 2020 19:55:17 |
| User entered 'Day 7' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:30:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T22:01:37', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'be7fe133-4011-44fa-a683-b733c97819a6' | System | 29 Sep 2020 03:01:58 |
| User entered 'Yes (Y)' | System | 29 Sep 2020 03:01:58 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:30:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T22:01:45', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'be7fe133-4011-44fa-a683-b733c97819a6' User entered '97.5' | System | 29 Sep 2020 03:01:58 |
| | System | 29 Sep 2020 03:01:58 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T22:01:49', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'be7fe133-4011-44fa-a683-b733c97819a6' | System | 29 Sep 2020 03:01:58 |
| User entered 'No (N)' | System | 29 Sep 2020 03:01:58 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T22:01:54', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'be7fe133-4011-44fa-a683-b733c97819a6' User entered '28 Sep 2020 22:01' | System | 29 Sep 2020 03:01:58 |
| | System | 29 Sep 2020 03:01:58 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '28 Sep 2020 12:00' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '29 Sep 2020 11:59' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 22 Sep 2020 19:55:17 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T15:18:37', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '422f410f-73c5-4dd1-8fa9-116a7e5e53b8' | System | 22 Sep 2020 20:18:55 |
| User entered 'None (1)' | System | 22 Sep 2020 20:18:55 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T15:18:40', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '422f410f-73c5-4dd1-8fa9-116a7e5e53b8' | System | 22 Sep 2020 20:18:55 |
| User entered 'No (N)' | System | 22 Sep 2020 20:18:55 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T15:18:42', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '422f410f-73c5-4dd1-8fa9-116a7e5e53b8' | System | 22 Sep 2020 20:18:55 |
| User entered 'No (N)' | System | 22 Sep 2020 20:18:55 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T15:18:49', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '422f410f-73c5-4dd1-8fa9-116a7e5e53b8' | System | 22 Sep 2020 20:18:55 |
| User entered 'None (1)' | System | 22 Sep 2020 20:18:55 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T15:18:52', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '422f410f-73c5-4dd1-8fa9-116a7e5e53b8' User entered '22 Sep 2020 15:18' | System | 22 Sep 2020 20:18:55 |
| | System | 22 Sep 2020 20:18:55 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '22 Sep 2020 15:05' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '22 Sep 2020 17:35' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 22 Sep 2020 19:55:17 |
| User entered 'Day 1, after vaccination (at home)' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T21:15:12', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'be590ce8-e7e5-4cfd-bc6d-de6ff7c76fcf' | System | 23 Sep 2020 02:15:49 |
| User entered 'None (1)' | System | 23 Sep 2020 02:15:49 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T21:15:28', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'be590ce8-e7e5-4cfd-bc6d-de6ff7c76fcf' User entered 'No (N)' | System | 23 Sep 2020 02:15:49 |
| | System | 23 Sep 2020 02:15:49 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T21:15:35', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'be590ce8-e7e5-4cfd-bc6d-de6ff7c76fcf' User entered 'No (N)' | System | 23 Sep 2020 02:15:49 |
| | System | 23 Sep 2020 02:15:49 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T21:15:39', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'be590ce8-e7e5-4cfd-bc6d-de6ff7c76fcf' | System | 23 Sep 2020 02:15:49 |
| User entered 'None (1)' | System | 23 Sep 2020 02:15:49 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T21:15:46', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'be590ce8-e7e5-4cfd-bc6d-de6ff7c76fcf' User entered '22 Sep 2020 21:15' | System | 23 Sep 2020 02:15:49 |
| | System | 23 Sep 2020 02:15:49 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '22 Sep 2020 18:30' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '23 Sep 2020 11:59' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 22 Sep 2020 19:55:17 |
| User entered 'Day 2' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-23T20:41:45', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'c6dd76c7-0494-40f1-849a-9a4d58d440db' User entered 'Does not interfere with activity (2)' | System | 24 Sep 2020 01:51:59 |
| | System | 24 Sep 2020 01:51:59 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:30:59

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-23T20:41:51', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'c6dd76c7-0494-40f1-849a-9a4d58d440db' User entered 'No (N)' | System | 24 Sep 2020 01:51:59 |
| | System | 24 Sep 2020 01:51:59 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-23T20:41:58', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'c6dd76c7-0494-40f1-849a-9a4d58d440db' User entered 'Yes (Y)' | System | 24 Sep 2020 01:51:59 |
| | System | 24 Sep 2020 01:51:59 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:30:59

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) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-23T20:51:35', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'c6dd76c7-0494-40f1-849a-9a4d58d440db' User entered '90' | System | 24 Sep 2020 01:51:59 |
| | System | 24 Sep 2020 01:51:59 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-23T20:51:44', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'c6dd76c7-0494-40f1-849a-9a4d58d440db' User entered 'None (1)' | System | 24 Sep 2020 01:51:59 |
| | System | 24 Sep 2020 01:51:59 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-23T20:51:54', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'c6dd76c7-0494-40f1-849a-9a4d58d440db' User entered '23 Sep 2020 20:51' | System | 24 Sep 2020 01:51:59 |
| | System | 24 Sep 2020 01:51:59 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '23 Sep 2020 12:00' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '24 Sep 2020 11:59' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 22 Sep 2020 19:55:17 |
| User entered 'Day 3' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-24T20:42:39', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '8213589c-ac6a-442e-a40e-167002bbf59a' | System | 25 Sep 2020 01:42:58 |
| User entered 'Does not interfere with activity (2)' | System | 25 Sep 2020 01:42:58 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:30:59

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-24T20:42:43', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '8213589c-ac6a-442e-a40e-167002bbf59a' User entered 'No (N)' | System | 25 Sep 2020 01:42:58 |
| | System | 25 Sep 2020 01:42:58 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-24T20:42:46', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '8213589c-ac6a-442e-a40e-167002bbf59a' User entered 'No (N)' | System | 25 Sep 2020 01:42:58 |
| | System | 25 Sep 2020 01:42:58 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-24T20:42:50', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '8213589c-ac6a-442e-a40e-167002bbf59a' User entered 'None (1)' | System | 25 Sep 2020 01:42:58 |
| | System | 25 Sep 2020 01:42:58 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-24T20:42:54', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '8213589c-ac6a-442e-a40e-167002bbf59a' User entered '24 Sep 2020 20:42' | System | 25 Sep 2020 01:42:58 |
| | System | 25 Sep 2020 01:42:58 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '24 Sep 2020 12:00' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '25 Sep 2020 11:59' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 22 Sep 2020 19:55:17 |
| User entered 'Day 4' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-25T20:25:46', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'fa21c30e-3faf-4f64-96e7-9c2e888d4ce1' | System | 26 Sep 2020 01:26:51 |
| User entered 'None (1)' | System | 26 Sep 2020 01:26:51 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:30:59

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-25T20:26:04', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'fa21c30e-3faf-4f64-96e7-9c2e888d4ce1' User entered 'No (N)' | System | 26 Sep 2020 01:26:51 |
| | System | 26 Sep 2020 01:26:51 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-25T20:26:24', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'fa21c30e-3faf-4f64-96e7-9c2e888d4ce1' | System | 26 Sep 2020 01:26:51 |
| User entered 'No (N)' | System | 26 Sep 2020 01:26:51 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-25T20:26:36', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'fa21c30e-3faf-4f64-96e7-9c2e888d4ce1' User entered 'None (1)' | System | 26 Sep 2020 01:26:51 |
| | System | 26 Sep 2020 01:26:51 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-25T20:26:48', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'fa21c30e-3faf-4f64-96e7-9c2e888d4ce1' | System | 26 Sep 2020 01:26:51 |
| User entered '25 Sep 2020 20:26' | System | 26 Sep 2020 01:26:51 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '25 Sep 2020 12:00' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '26 Sep 2020 11:59' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 22 Sep 2020 19:55:17 |
| User entered 'Day 5' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:30:59

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:30:59

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) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:30:59

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) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '26 Sep 2020 12:00' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '27 Sep 2020 11:59' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 22 Sep 2020 19:55:17 |
| User entered 'Day 6' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T06:41:30', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '608d4420-c944-4315-a21d-04600a68801c' User entered 'None (1)' | System | 28 Sep 2020 11:41:49 |
| | System | 28 Sep 2020 11:41:49 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:30:59

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T06:41:35', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '608d4420-c944-4315-a21d-04600a68801c' User entered 'No (N)' | System | 28 Sep 2020 11:41:49 |
| | System | 28 Sep 2020 11:41:49 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T06:41:38', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '608d4420-c944-4315-a21d-04600a68801c' User entered 'No (N)' | System | 28 Sep 2020 11:41:49 |
| | System | 28 Sep 2020 11:41:49 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T06:41:44', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '608d4420-c944-4315-a21d-04600a68801c' User entered 'None (1)' | System | 28 Sep 2020 11:41:49 |
| | System | 28 Sep 2020 11:41:49 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T06:41:46', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '608d4420-c944-4315-a21d-04600a68801c' User entered '28 Sep 2020 06:41' | System | 28 Sep 2020 11:41:49 |
| | System | 28 Sep 2020 11:41:49 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '27 Sep 2020 12:00' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '28 Sep 2020 11:59' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 22 Sep 2020 19:55:17 |
| User entered 'Day 7' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T22:02:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'f7ccf5d7-ee27-4311-b19b-959b19457401' User entered 'None (1)' | System | 29 Sep 2020 03:02:26 |
| | System | 29 Sep 2020 03:02:26 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:30:59

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T22:02:09', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'f7ccf5d7-ee27-4311-b19b-959b19457401' User entered 'No (N)' | System | 29 Sep 2020 03:02:26 |
| | System | 29 Sep 2020 03:02:26 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T22:02:12', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'f7ccf5d7-ee27-4311-b19b-959b19457401' User entered 'No (N)' | System | 29 Sep 2020 03:02:26 |
| | System | 29 Sep 2020 03:02:26 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:30:59

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T22:02:15', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'f7ccf5d7-ee27-4311-b19b-959b19457401' User entered 'None (1)' | System | 29 Sep 2020 03:02:26 |
| | System | 29 Sep 2020 03:02:26 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:30:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T22:02:21', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'f7ccf5d7-ee27-4311-b19b-959b19457401' User entered '28 Sep 2020 22:02' | System | 29 Sep 2020 03:02:26 |
| | System | 29 Sep 2020 03:02:26 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '28 Sep 2020 12:00' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '29 Sep 2020 11:59' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 22 Sep 2020 19:55:17 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T15:18:57', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '6d03b3a3-2d1a-4e11-ad95-2ca5c99b240a' User entered 'None (0)' | System | 22 Sep 2020 20:19:16 |
| | System | 22 Sep 2020 20:19:16 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T15:18:59', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '6d03b3a3-2d1a-4e11-ad95-2ca5c99b240a' User entered 'None (0)' | System | 22 Sep 2020 20:19:16 |
| | System | 22 Sep 2020 20:19:16 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T15:19:01', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '6d03b3a3-2d1a-4e11-ad95-2ca5c99b240a' User entered 'None (0)' | System | 22 Sep 2020 20:19:16 |
| | System | 22 Sep 2020 20:19:16 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T15:19:02', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '6d03b3a3-2d1a-4e11-ad95-2ca5c99b240a' User entered 'None (0)' | System | 22 Sep 2020 20:19:16 |
| | System | 22 Sep 2020 20:19:16 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T15:19:04', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '6d03b3a3-2d1a-4e11-ad95-2ca5c99b240a' User entered 'None (0)' | System | 22 Sep 2020 20:19:16 |
| | System | 22 Sep 2020 20:19:16 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T15:19:06', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '6d03b3a3-2d1a-4e11-ad95-2ca5c99b240a' User entered 'None (0)' | System | 22 Sep 2020 20:19:16 |
| | System | 22 Sep 2020 20:19:16 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T15:19:11', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '6d03b3a3-2d1a-4e11-ad95-2ca5c99b240a' User entered 'No (N)' | System | 22 Sep 2020 20:19:16 |
| | System | 22 Sep 2020 20:19:16 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T15:19:13', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '6d03b3a3-2d1a-4e11-ad95-2ca5c99b240a' User entered '22 Sep 2020 15:19' | System | 22 Sep 2020 20:19:16 |
| | System | 22 Sep 2020 20:19:16 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '22 Sep 2020 15:05' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '22 Sep 2020 17:35' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 22 Sep 2020 19:55:17 |
| User entered 'Day 1, after vaccination (at home)' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T21:16:35', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '0d855bee-c6a1-4468-be93-8cf92cb60281' User entered 'None (0)' | System | 23 Sep 2020 02:17:01 |
| | System | 23 Sep 2020 02:17:01 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T21:16:37', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '0d855bee-c6a1-4468-be93-8cf92cb60281' User entered 'None (0)' | System | 23 Sep 2020 02:17:01 |
| | System | 23 Sep 2020 02:17:01 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T21:16:40', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '0d855bee-c6a1-4468-be93-8cf92cb60281' User entered 'None (0)' | System | 23 Sep 2020 02:17:01 |
| | System | 23 Sep 2020 02:17:01 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T21:16:43', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '0d855bee-c6a1-4468-be93-8cf92cb60281' User entered 'None (0)' | System | 23 Sep 2020 02:17:01 |
| | System | 23 Sep 2020 02:17:01 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T21:16:46', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '0d855bee-c6a1-4468-be93-8cf92cb60281' User entered 'None (0)' | System | 23 Sep 2020 02:17:01 |
| | System | 23 Sep 2020 02:17:01 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T21:16:50', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '0d855bee-c6a1-4468-be93-8cf92cb60281' User entered 'None (0)' | System | 23 Sep 2020 02:17:01 |
| | System | 23 Sep 2020 02:17:01 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T21:16:55', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '0d855bee-c6a1-4468-be93-8cf92cb60281' User entered 'No (N)' | System | 23 Sep 2020 02:17:01 |
| | System | 23 Sep 2020 02:17:01 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-22T21:16:58', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '0d855bee-c6a1-4468-be93-8cf92cb60281' User entered '22 Sep 2020 21:16' | System | 23 Sep 2020 02:17:01 |
| | System | 23 Sep 2020 02:17:01 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '22 Sep 2020 18:30' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '23 Sep 2020 11:59' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 22 Sep 2020 19:55:17 |
| User entered 'Day 2' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-23T20:47:20', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'cc07652b-441b-4d92-b203-cc85bc2cf7d0' User entered 'None (0)' | System | 24 Sep 2020 01:48:07 |
| | System | 24 Sep 2020 01:48:07 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-23T20:47:21', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'cc07652b-441b-4d92-b203-cc85bc2cf7d0' User entered 'None (0)' | System | 24 Sep 2020 01:48:07 |
| | System | 24 Sep 2020 01:48:07 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-23T20:47:24', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'cc07652b-441b-4d92-b203-cc85bc2cf7d0' User entered 'None (0)' | System | 24 Sep 2020 01:48:07 |
| | System | 24 Sep 2020 01:48:07 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-23T20:47:36', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'cc07652b-441b-4d92-b203-cc85bc2cf7d0' | System | 24 Sep 2020 01:48:07 |
| User entered 'No interference with activity (1)' | System | 24 Sep 2020 01:48:07 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-23T20:47:39', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'cc07652b-441b-4d92-b203-cc85bc2cf7d0' User entered 'None (0)' | System | 24 Sep 2020 01:48:07 |
| | System | 24 Sep 2020 01:48:07 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-23T20:47:44', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'cc07652b-441b-4d92-b203-cc85bc2cf7d0' | System | 24 Sep 2020 01:48:07 |
| User entered 'No interference with activity (1)' | System | 24 Sep 2020 01:48:07 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-23T20:47:47', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'cc07652b-441b-4d92-b203-cc85bc2cf7d0' | System | 24 Sep 2020 01:48:07 |
| User entered 'No (N)' | System | 24 Sep 2020 01:48:07 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-23T20:48:02', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'cc07652b-441b-4d92-b203-cc85bc2cf7d0' User entered '23 Sep 2020 20:48' | System | 24 Sep 2020 01:48:07 |
| | System | 24 Sep 2020 01:48:07 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '23 Sep 2020 12:00' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '24 Sep 2020 11:59' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 22 Sep 2020 19:55:17 |
| User entered 'Day 3' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-24T20:43:01', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'cfa8ef0f-3149-48ca-9d34-f99f52e9b43f' User entered 'None (0)' | System | 25 Sep 2020 01:43:20 |
| | System | 25 Sep 2020 01:43:20 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-24T20:43:02', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'cfa8ef0f-3149-48ca-9d34-f99f52e9b43f' User entered 'None (0)' | System | 25 Sep 2020 01:43:20 |
| | System | 25 Sep 2020 01:43:20 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-24T20:43:04', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'cfa8ef0f-3149-48ca-9d34-f99f52e9b43f' User entered 'None (0)' | System | 25 Sep 2020 01:43:20 |
| | System | 25 Sep 2020 01:43:20 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-24T20:43:06', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'cfa8ef0f-3149-48ca-9d34-f99f52e9b43f' User entered 'None (0)' | System | 25 Sep 2020 01:43:20 |
| | System | 25 Sep 2020 01:43:20 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-24T20:43:08', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'cfa8ef0f-3149-48ca-9d34-f99f52e9b43f' User entered 'None (0)' | System | 25 Sep 2020 01:43:20 |
| | System | 25 Sep 2020 01:43:20 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-24T20:43:10', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'cfa8ef0f-3149-48ca-9d34-f99f52e9b43f' User entered 'None (0)' | System | 25 Sep 2020 01:43:20 |
| | System | 25 Sep 2020 01:43:20 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-24T20:43:13', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'cfa8ef0f-3149-48ca-9d34-f99f52e9b43f' User entered 'No (N)' | System | 25 Sep 2020 01:43:20 |
| | System | 25 Sep 2020 01:43:20 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-24T20:43:18', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'cfa8ef0f-3149-48ca-9d34-f99f52e9b43f' User entered '24 Sep 2020 20:43' | System | 25 Sep 2020 01:43:20 |
| | System | 25 Sep 2020 01:43:20 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '24 Sep 2020 12:00' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '25 Sep 2020 11:59' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 22 Sep 2020 19:55:17 |
| User entered 'Day 4' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-25T20:26:55', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'ac311747-e497-40a3-8ae2-3f27394951e2' User entered 'None (0)' | System | 26 Sep 2020 01:31:59 |
| | System | 26 Sep 2020 01:31:59 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-25T20:26:58', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'ac311747-e497-40a3-8ae2-3f27394951e2' User entered 'None (0)' | System | 26 Sep 2020 01:31:59 |
| | System | 26 Sep 2020 01:31:59 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-25T20:27:02', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'ac311747-e497-40a3-8ae2-3f27394951e2' User entered 'None (0)' | System | 26 Sep 2020 01:31:59 |
| | System | 26 Sep 2020 01:31:59 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-25T20:27:08', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'ac311747-e497-40a3-8ae2-3f27394951e2' User entered 'None (0)' | System | 26 Sep 2020 01:31:59 |
| | System | 26 Sep 2020 01:31:59 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-25T20:27:24', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'ac311747-e497-40a3-8ae2-3f27394951e2' User entered 'None (0)' | System | 26 Sep 2020 01:31:59 |
| | System | 26 Sep 2020 01:31:59 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-25T20:27:27', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'ac311747-e497-40a3-8ae2-3f27394951e2' User entered 'None (0)' | System | 26 Sep 2020 01:31:59 |
| | System | 26 Sep 2020 01:31:59 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-25T20:27:35', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'ac311747-e497-40a3-8ae2-3f27394951e2' User entered 'No (N)' | System | 26 Sep 2020 01:31:59 |
| | System | 26 Sep 2020 01:31:59 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-25T20:31:57', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'ac311747-e497-40a3-8ae2-3f27394951e2' User entered '25 Sep 2020 20:31' | System | 26 Sep 2020 01:31:59 |
| | System | 26 Sep 2020 01:31:59 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '25 Sep 2020 12:00' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '26 Sep 2020 11:59' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 22 Sep 2020 19:55:17 |
| User entered 'Day 5' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:30:59

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:30:59

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:30:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:30:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:30:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:30:59

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:30:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '26 Sep 2020 12:00' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '27 Sep 2020 11:59' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 22 Sep 2020 19:55:17 |
| User entered 'Day 6' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T06:41:50', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '23cb48d1-f82e-4b13-9d24-2edeaf730ff2' User entered 'None (0)' | System | 28 Sep 2020 11:42:10 |
| | System | 28 Sep 2020 11:42:10 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T06:41:52', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '23cb48d1-f82e-4b13-9d24-2edeaf730ff2' | System | 28 Sep 2020 11:42:10 |
| User entered 'None (0)' | System | 28 Sep 2020 11:42:10 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T06:41:53', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '23cb48d1-f82e-4b13-9d24-2edeaf730ff2' User entered 'None (0)' | System | 28 Sep 2020 11:42:10 |
| | System | 28 Sep 2020 11:42:10 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T06:41:55', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '23cb48d1-f82e-4b13-9d24-2edeaf730ff2' User entered 'None (0)' | System | 28 Sep 2020 11:42:10 |
| | System | 28 Sep 2020 11:42:10 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T06:41:57', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '23cb48d1-f82e-4b13-9d24-2edeaf730ff2' User entered 'None (0)' | System | 28 Sep 2020 11:42:10 |
| | System | 28 Sep 2020 11:42:10 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T06:41:59', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '23cb48d1-f82e-4b13-9d24-2edeaf730ff2' User entered 'None (0)' | System | 28 Sep 2020 11:42:10 |
| | System | 28 Sep 2020 11:42:10 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T06:42:02', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '23cb48d1-f82e-4b13-9d24-2edeaf730ff2' | System | 28 Sep 2020 11:42:10 |
| User entered 'No (N)' | System | 28 Sep 2020 11:42:10 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T06:42:07', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '23cb48d1-f82e-4b13-9d24-2edeaf730ff2' User entered '28 Sep 2020 06:42' | System | 28 Sep 2020 11:42:10 |
| | System | 28 Sep 2020 11:42:10 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '27 Sep 2020 12:00' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '28 Sep 2020 11:59' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 22 Sep 2020 19:55:17 |
| User entered 'Day 7' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T22:02:26', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '46aba39c-5c14-417b-a54e-cfd64a3de031' User entered 'None (0)' | System | 29 Sep 2020 03:02:44 |
| | System | 29 Sep 2020 03:02:44 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T22:02:28', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '46aba39c-5c14-417b-a54e-cfd64a3de031' User entered 'None (0)' | System | 29 Sep 2020 03:02:44 |
| | System | 29 Sep 2020 03:02:44 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T22:02:30', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '46aba39c-5c14-417b-a54e-cfd64a3de031' User entered 'None (0)' | System | 29 Sep 2020 03:02:44 |
| | System | 29 Sep 2020 03:02:44 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T22:02:31', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '46aba39c-5c14-417b-a54e-cfd64a3de031' User entered 'None (0)' | System | 29 Sep 2020 03:02:44 |
| | System | 29 Sep 2020 03:02:44 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T22:02:33', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '46aba39c-5c14-417b-a54e-cfd64a3de031' User entered 'None (0)' | System | 29 Sep 2020 03:02:44 |
| | System | 29 Sep 2020 03:02:44 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T22:02:35', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '46aba39c-5c14-417b-a54e-cfd64a3de031' User entered 'None (0)' | System | 29 Sep 2020 03:02:44 |
| | System | 29 Sep 2020 03:02:44 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T22:02:40', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '46aba39c-5c14-417b-a54e-cfd64a3de031' User entered 'No (N)' | System | 29 Sep 2020 03:02:44 |
| | System | 29 Sep 2020 03:02:44 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-09-28T22:02:42', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '46aba39c-5c14-417b-a54e-cfd64a3de031' User entered '28 Sep 2020 22:02' | System | 29 Sep 2020 03:02:44 |
| | System | 29 Sep 2020 03:02:44 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '28 Sep 2020 12:00' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:30:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| User entered '29 Sep 2020 11:59' | System | 22 Sep 2020 19:55:17 |

US3292312

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 14:27:50 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 29 Sep 2020 20:24:50 |

US3292312

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 14:27:50 |
| User entered '29 Sep 2020' | (b) (4), (b) (6) | 29 Sep 2020 20:24:50 |

US3292312

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:27:50 |
| User entered 'Contact Made (CONTACT MADE)' | | 29 Sep 2020 20:24:50 |

US3292312

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 14:27:50 |
| User entered empty. | (b) (4), (b) (6) | 29 Sep 2020 20:24:50 |

US3292312

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) | 29 Jan 2021 14:27:54 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 29 Sep 2020 20:25:31 |

US3292312

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered 'l' | System | 29 Sep 2020 20:25:31 |

US3292312

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Oct 2020 21:10:09 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 06 Oct 2020 19:04:01 |

US3292312

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Oct 2020 21:10:09 |
| User entered '6 Oct 2020' | Kristy Trevino (b) (4) | 06 Oct 2020 19:04:01 |

US3292312

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Oct 2020 21:10:09 |
| User entered 'Contact Made (CONTACT MADE)' | Kristy Trevino (b) (4) (b) (4) | 06 Oct 2020 19:04:01 |

US3292312

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Oct 2020 21:10:09 |
| User entered empty. | Kristy Trevino (b) (4) | 06 Oct 2020 19:04:01 |

US3292312

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Oct 2020 21:10:14 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 06 Oct 2020 19:04:08 |

US3292312

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered 'l' | System | 06 Oct 2020 19:04:08 |

US3292312

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:29:59 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) | 13 Oct 2020 19:00:43 |

US3292312

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:29:59 |
| User entered '13 Oct 2020' | Kristy Trevino (b) (4) | 13 Oct 2020 19:00:43 |

US3292312

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:29:59 |
| User entered 'Contact Made (CONTACT MADE)' | Kristy Trevino (b) (4) | 13 Oct 2020 19:00:43 |

US3292312

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:29:59 |
| User entered empty. | Kristy Trevino (b) (4) | 13 Oct 2020 19:00:43 |

US3292312

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:30:04 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) | 13 Oct 2020 19:00:49 |

US3292312

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered 'l' | System | 13 Oct 2020 19:00:49 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:30:59

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:32:26 |
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) | 22 Oct 2020 19:14:57 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:32:26 |
| User entered '22 Oct 2020' | Gerardo Pena (b) (4) | 22 Oct 2020 19:14:57 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:32:26 |
| User entered 'Clinic (Clinic)' | Gerardo Pena (b) (4) | 22 Oct 2020 19:14:57 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:30:59

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User entered 'VISIT3' | System | 22 Oct 2020 19:14:57 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:32:45 |
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) | 22 Oct 2020 19:16:16 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:32:45 |
| User entered '22 Oct 2020' | Gerardo Pena (b) (4) | 22 Oct 2020 19:16:16 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:32:45 |
| User entered '11:17' | Gerardo Pena (b) (4) | 22 Oct 2020 19:16:16 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User entered '22 Oct 2020 11:17' | System | 22 Oct 2020 19:16:16 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:32:45 |
| User entered '36.4' C | Gerardo Pena (b) (4) | 22 Oct 2020 19:16:16 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:32:45 |
| User entered 'Oral (Oral)' | Gerardo Pena (b) (4) | 22 Oct 2020 19:16:16 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:32:45 |
| User entered empty. | Gerardo Pena (b) (4) | 22 Oct 2020 19:16:16 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:32:45 |
| User entered '59' | Gerardo Pena (b) (4) | 22 Oct 2020 19:16:16 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User entered 'bpm' | System | 22 Oct 2020 19:16:16 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:32:45 |
| User entered '14' | Gerardo Pena (b) (4) | 22 Oct 2020 19:16:16 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User entered 'breaths/min' | System | 22 Oct 2020 19:16:16 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:32:45 |
| User entered '127' | Gerardo Pena (b) (4) | 22 Oct 2020 19:16:16 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User entered 'mmHg' | System | 22 Oct 2020 19:16:16 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:32:45 |
| User entered '81' | Gerardo Pena (b) (4) | 22 Oct 2020 19:16:16 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User entered 'mmHg' | System | 22 Oct 2020 19:16:16 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:30:59

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:34:08 |
| User entered 'No (N)' | Gerardo Pena (b) (4) | 22 Oct 2020 19:16:20 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:30:59

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:34:08 |
| User entered empty. | Gerardo Pena (b) (4) | 22 Oct 2020 19:16:20 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:30:59

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:34:15 |
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) | 22 Oct 2020 19:16:31 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:30:59

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:34:15 |
| User entered '22 Oct 2020' | Gerardo Pena (b) (4) | 22 Oct 2020 19:16:31 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:30:59

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:34:15 |
| User entered '11:30' | Gerardo Pena (b) (4) | 22 Oct 2020 19:16:31 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:30:59

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User entered '22 Oct 2020 11:30' | System | 22 Oct 2020 19:16:31 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Jan 2021 14:34:35 |
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) | 22 Oct 2020 19:16:33 |

US3292312

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:23 |
| User entered 'I' | System | 22 Oct 2020 19:16:33 |

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 64' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-10-26T13:19:04', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'f2a0d486-5971-4b19-b976-b031cc1dc717' | System | 26 Oct 2020 18:20:18 |
| User entered 'Yes (Y)' | System | 26 Oct 2020 18:20:18 |

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-10-26T13:19:08', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'f2a0d486-5971-4b19-b976-b031cc1dc717' | System | 26 Oct 2020 18:20:18 |
| User entered 'No (N)' | System | 26 Oct 2020 18:20:18 |

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-10-26T13:19:14', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'f2a0d486-5971-4b19-b976-b031cc1dc717' | System | 26 Oct 2020 18:20:18 |
| User entered 'No (N)' | System | 26 Oct 2020 18:20:18 |

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-10-26T13:19:39', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'f2a0d486-5971-4b19-b976-b031cc1dc717' | System | 26 Oct 2020 18:20:18 |
| User entered 'Yes (Y)' | System | 26 Oct 2020 18:20:18 |

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Please 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) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-10-26T13:19:52', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'f2a0d486-5971-4b19-b976-b031cc1dc717' | System | 26 Oct 2020 18:20:18 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 26 Oct 2020 18:20:18 |

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-10-26T13:20:05', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'f2a0d486-5971-4b19-b976-b031cc1dc717' User entered '26 Oct 2020 13:20:05' | System | 26 Oct 2020 18:20:18 |
| | System | 26 Oct 2020 18:20:18 |

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered '25 Oct 2020 00:01' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered '29 Oct 2020 23:59' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 71' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-11-03T18:33:29', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'ffd23ba3-eeba-4591-9a40-686cbac7f3e5' | System | 04 Nov 2020 00:33:59 |
| User entered 'Yes (Y)' | System | 04 Nov 2020 00:33:59 |

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-11-03T18:33:34', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'ffd23ba3-eeba-4591-9a40-686cbac7f3e5' | System | 04 Nov 2020 00:33:59 |
| User entered 'No (N)' | System | 04 Nov 2020 00:33:59 |

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-11-03T18:33:40', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'ffd23ba3-eeba-4591-9a40-686cbac7f3e5' | System | 04 Nov 2020 00:33:59 |
| User entered 'No (N)' | System | 04 Nov 2020 00:33:59 |

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-11-03T18:33:52', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'ffd23ba3-ceba-4591-9a40-686cbac7f3e5' | System | 04 Nov 2020 00:33:59 |
| User entered 'No (N)' | System | 04 Nov 2020 00:33:59 |

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-11-03T18:33:56', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'ffd23ba3-eeba-4591-9a40-686ebae7f3e5' User entered '03 Nov 2020 18:33:56' | System | 04 Nov 2020 00:33:59 |
| | System | 04 Nov 2020 00:33:59 |

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered '01 Nov 2020 00:01' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered '05 Nov 2020 23:59' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered 'Day 78' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-11-11T10:29:15', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'fe83e22e-126f-47e4-8e41-ab1042ff7ed5' | System | 11 Nov 2020 16:29:36 |
| User entered 'No (N)' | System | 11 Nov 2020 16:29:36 |

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-11-11T10:29:22', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'fe83e22e-126f-47e4-8e41-ab1042ff7ed5' | System | 11 Nov 2020 16:29:36 |
| User entered 'No (N)' | System | 11 Nov 2020 16:29:36 |

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-11-11T10:29:33', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'fe83e22e-126f-47e4-8e41-ab1042ff7ed5' User entered '11 Nov 2020 10:29:33' | System | 11 Nov 2020 16:29:36 |
| | System | 11 Nov 2020 16:29:36 |

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered '08 Nov 2020 00:01' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 20:24:05 |
| Data entry locked. | System | 25 Aug 2020 20:11:33 |
| User entered '12 Nov 2020 23:59' | System | 25 Aug 2020 20:11:33 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 89' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-11-23T13:03:12', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '99e1d566-a814-4a16-9464-1a7afe605b95' User entered 'No (N)' | System | 23 Nov 2020 19:03:23 |
| | System | 23 Nov 2020 19:03:23 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

Have you been exposed to someone with 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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-11-23T13:03:17', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '99e1d566-a814-4a16-9464-1a7afe605b95' User entered 'No (N)' | System | 23 Nov 2020 19:03:23 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-11-23T13:03:20', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '99e1d566-a814-4a16-9464-1a7afe605b95' User entered '23 Nov 2020 13:03:20' | System | 23 Nov 2020 19:03:23 |
| | System | 23 Nov 2020 19:03:23 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '19 Nov 2020 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '23 Nov 2020 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-11-30T13:27:26', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'c5b42afe-0d15-4a22-b3bb-6ff14f3bec6c' User entered 'No (N)' | System | 30 Nov 2020 19:27:42 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Have you been exposed to someone with 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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-11-30T13:27:33', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'c5b42afe-0d15-4a22-b3bb-6ff14f3bec6c' User entered 'No (N)' | System | 30 Nov 2020 19:27:42 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-11-30T13:27:37', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'c5b42afe-0d15-4a22-b3bb-6ff14f3bec6c' User entered '30 Nov 2020 13:27:37' | System | 30 Nov 2020 19:27:42 |
| | System | 30 Nov 2020 19:27:42 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '26 Nov 2020 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '30 Nov 2020 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-12-07T17:23:38', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '4cd7fe5b-1e0b-4544-87cd-6a51b4a83fde' User entered 'No (N)' | System | 07 Dec 2020 23:23:48 |
| | System | 07 Dec 2020 23:23:48 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Have you been exposed to someone with 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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-12-07T17:23:42', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '4cd7fe5b-1e0b-4544-87cd-6a51b4a83fde' User entered 'No (N)' | System | 07 Dec 2020 23:23:48 |
| | System | 07 Dec 2020 23:23:48 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-12-07T17:23:45', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '4cd7fe5b-1e0b-4544-87cd-6a51b4a83fde' User entered '07 Dec 2020 17:23:45' | System | 07 Dec 2020 23:23:48 |
| | System | 07 Dec 2020 23:23:48 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '03 Dec 2020 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '07 Dec 2020 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-12-10T10:37:58', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '3d7ee215-9acb-490b-b3db-32c0f97a7a27' | System | 10 Dec 2020 16:38:11 |
| User entered 'No (N)' | System | 10 Dec 2020 16:38:11 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Have you been exposed to someone with 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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-12-10T10:38:03', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '3d7ee215-9acb-490b-b3db-32c0f97a7a27' | System | 10 Dec 2020 16:38:11 |
| User entered 'No (N)' | System | 10 Dec 2020 16:38:11 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-12-10T10:38:06', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '3d7ee215-9acb-490b-b3db-32c0f97a7a27' User entered '10 Dec 2020 10:38:06' | System | 10 Dec 2020 16:38:11 |
| | System | 10 Dec 2020 16:38:11 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '10 Dec 2020 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '14 Dec 2020 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-12-17T22:30:42', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '5a2b5d7f-bf52-4641-99c9-b0e86ea9193b' User entered 'No (N)' | System | 18 Dec 2020 04:30:57 |
| | System | 18 Dec 2020 04:30:57 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Have you been exposed to someone with 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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-12-17T22:30:50', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '5a2b5d7f-bf52-4641-99c9-b0e86ea9193b' User entered 'No (N)' | System | 18 Dec 2020 04:30:57 |
| | System | 18 Dec 2020 04:30:57 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-12-17T22:30:53', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '5a2b5d7f-bf52-4641-99c9-b0e86ea9193b' User entered '17 Dec 2020 22:30:53' | System | 18 Dec 2020 04:30:57 |
| | System | 18 Dec 2020 04:30:57 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '17 Dec 2020 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '21 Dec 2020 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-12-26T13:09:10', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '3d448aef-772b-4569-ab03-4f4b52c5fbb1' User entered 'No (N)' | System | 26 Dec 2020 19:09:35 |
| | System | 26 Dec 2020 19:09:35 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Have you been exposed to someone with 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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-12-26T13:09:14', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '3d448aef-772b-4569-ab03-4f4b52c5fbb1' User entered 'No (N)' | System | 26 Dec 2020 19:09:35 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2020-12-26T13:09:32', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '3d448aef-772b-4569-ab03-4f4b52c5fbb1' User entered '26 Dec 2020 13:09:32' | System | 26 Dec 2020 19:09:35 |
| | System | 26 Dec 2020 19:09:35 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '24 Dec 2020 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '28 Dec 2020 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-01-01T18:04:15', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '3f1fbaba-3e9b-477c-9690-97170a1fd8f6' | System | 02 Jan 2021 00:04:31 |
| User entered 'No (N)' | System | 02 Jan 2021 00:04:31 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

Have you been exposed to someone with 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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-01-01T18:04:26', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '3f1fbaba-3e9b-477c-9690-97170a1fd8f6' | System | 02 Jan 2021 00:04:31 |
| User entered 'No (N)' | System | 02 Jan 2021 00:04:31 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-01-01T18:04:29', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '3f1fbaba-3e9b-477c-9690-97170a1fd8f6' | System | 02 Jan 2021 00:04:31 |
| User entered '01 Jan 2021 18:04:29' | System | 02 Jan 2021 00:04:31 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '31 Dec 2020 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '04 Jan 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-01-11T16:42:51', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'f1925c2f-d76c-4517-83bc-a0e76904df33' | System | 11 Jan 2021 22:43:05 |
| User entered 'No (N)' | System | 11 Jan 2021 22:43:05 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Have you been exposed to someone with 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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-01-11T16:42:54', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'f1925c2f-d76c-4517-83bc-a0e76904df33' | System | 11 Jan 2021 22:43:05 |
| User entered 'No (N)' | System | 11 Jan 2021 22:43:05 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-01-11T16:43:01', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'f1925c2f-d76c-4517-83bc-a0e76904df33' | System | 11 Jan 2021 22:43:05 |
| User entered '11 Jan 2021 16:43:01' | System | 11 Jan 2021 22:43:05 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '07 Jan 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '11 Jan 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-01-17T21:56:15', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'cdda5804-94fa-412c-bf85-29cf7ee159b0' | System | 18 Jan 2021 03:56:36 |
| User entered 'No (N)' | System | 18 Jan 2021 03:56:36 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Have you been exposed to someone with 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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-01-17T21:56:28', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'cdda5804-94fa-412c-bf85-29cf7ee159b0' | System | 18 Jan 2021 03:56:36 |
| User entered 'No (N)' | System | 18 Jan 2021 03:56:36 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-01-17T21:56:32', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'cdda5804-94fa-412c-bf85-29cf7ee159b0' User entered '17 Jan 2021 21:56:32' | System | 18 Jan 2021 03:56:36 |
| | System | 18 Jan 2021 03:56:36 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '14 Jan 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '18 Jan 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-01-21T14:12:15', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '085c673e-dbc8-4967-b580-0503d4b20765' User entered 'No (N)' | System | 21 Jan 2021 20:12:22 |
| | System | 21 Jan 2021 20:12:22 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Have you been exposed to someone with 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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-01-21T14:12:17', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '085c673e-dbc8-4967-b580-0503d4b20765' User entered 'No (N)' | System | 21 Jan 2021 20:12:22 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-01-21T14:12:20', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '085c673e-dbc8-4967-b580-0503d4b20765' User entered '21 Jan 2021 14:12:20' | System | 21 Jan 2021 20:12:22 |
| | System | 21 Jan 2021 20:12:22 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '21 Jan 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '25 Jan 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-01-28T16:20:55', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '600b1981-663f-4488-a217-57c06d777060' | System | 28 Jan 2021 22:21:08 |
| User entered 'No (N)' | System | 28 Jan 2021 22:21:08 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Have you been exposed to someone with 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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-01-28T16:20:59', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '600b1981-663f-4488-a217-57c06d777060' | System | 28 Jan 2021 22:21:08 |
| User entered 'No (N)' | System | 28 Jan 2021 22:21:08 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-01-28T16:21:04', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '600b1981-663f-4488-a217-57c06d777060' | System | 28 Jan 2021 22:21:08 |
| User entered '28 Jan 2021 16:21:04' | System | 28 Jan 2021 22:21:08 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '28 Jan 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '01 Feb 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-02-06T00:03:37', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '41628313-1550-4396-ba67-7c60babae2a9' User entered 'No (N)' | System | 06 Feb 2021 06:03:46 |
| | System | 06 Feb 2021 06:03:46 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

Have you been exposed to someone with 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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-02-06T00:03:40', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '41628313-1550-4396-ba67-7c60babae2a9' | System | 06 Feb 2021 06:03:46 |
| User entered 'No (N)' | System | 06 Feb 2021 06:03:46 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-02-06T00:03:43', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '41628313-1550-4396-ba67-7c60babae2a9' User entered '06 Feb 2021 00:03:43' | System | 06 Feb 2021 06:03:46 |
| | System | 06 Feb 2021 06:03:46 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '04 Feb 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '08 Feb 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-02-12T16:36:09', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'd58b3afe-cf21-4d7a-8bb0-0d6702dcf0d2' | System | 12 Feb 2021 22:36:17 |
| User entered 'No (N)' | System | 12 Feb 2021 22:36:17 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Have you been exposed to someone with 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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-02-12T16:36:11', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'd58b3afe-cf21-4d7a-8bb0-0d6702dcf0d2' | System | 12 Feb 2021 22:36:17 |
| User entered 'No (N)' | System | 12 Feb 2021 22:36:17 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-02-12T16:36:13', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'd58b3afe-cf21-4d7a-8bb0-0d6702dcf0d2' | System | 12 Feb 2021 22:36:17 |
| User entered '12 Feb 2021 16:36:13' | System | 12 Feb 2021 22:36:17 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '11 Feb 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '15 Feb 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-02-18T11:14:42', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '1afcadd6-54ec-4729-8652-6874db585cbb' User entered 'No (N)' | System | 18 Feb 2021 17:18:23 |
| | System | 18 Feb 2021 17:18:23 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

Have you been exposed to someone with 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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-02-18T11:14:47', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '1afcadd6-54ec-4729-8652-6874db585cbb' User entered 'No (N)' | System | 18 Feb 2021 17:18:23 |
| | System | 18 Feb 2021 17:18:23 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-02-18T11:14:50', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '1afcadd6-54ec-4729-8652-6874db585cbb' User entered '18 Feb 2021 11:14:50' | System | 18 Feb 2021 17:18:23 |
| | System | 18 Feb 2021 17:18:23 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '18 Feb 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '22 Feb 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-02-26T19:43:51-06:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '3863a47d-fe7b-47e9-9d30-d8a8f150ee55' | System | 27 Feb 2021 01:44:06 |
| User entered 'No (N)' | System | 27 Feb 2021 01:44:06 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Have you been exposed to someone with 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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-02-26T19:43:53-06:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '3863a47d-fe7b-47e9-9d30-d8a8f150ee55' | System | 27 Feb 2021 01:44:06 |
| User entered 'No (N)' | System | 27 Feb 2021 01:44:06 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-02-26T19:43:59-06:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '3863a47d-fe7b-47e9-9d30-d8a8f150ee55' | System | 27 Feb 2021 01:44:06 |
| User entered '27 Feb 2021 01:43:59' | System | 27 Feb 2021 01:44:06 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '25 Feb 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '01 Mar 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-03-04T11:14:36-06:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '1192dc64-0e02-49f0-9501-262c1cafecbe' User entered 'No (N)' | System | 04 Mar 2021 17:18:47 |
| | System | 04 Mar 2021 17:18:47 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Have you been exposed to someone with 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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-03-04T11:14:41-06:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '1192dc64-0e02-49f0-9501-262c1cafecbe' | System | 04 Mar 2021 17:18:47 |
| User entered 'No (N)' | System | 04 Mar 2021 17:18:47 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-03-04T11:14:45-06:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '1192dc64-0e02-49f0-9501-262c1cafecbe' User entered '04 Mar 2021 11:14:45' | System | 04 Mar 2021 17:18:47 |
| | System | 04 Mar 2021 17:18:47 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '04 Mar 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '08 Mar 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-03-11T07:00:21-06:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '23e12895-fe0c-42e0-b2c3-3bbd6a14d121' | System | 11 Mar 2021 13:00:35 |
| User entered 'No (N)' | System | 11 Mar 2021 13:00:35 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Have you been exposed to someone with 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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-03-11T07:00:25-06:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '23e12895-fe0c-42e0-b2c3-3bbd6a14d121' | System | 11 Mar 2021 13:00:35 |
| User entered 'No (N)' | System | 11 Mar 2021 13:00:35 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-03-11T07:00:30-06:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '23e12895-fe0c-42e0-b2c3-3bbd6a14d121' | System | 11 Mar 2021 13:00:35 |
| User entered '11 Mar 2021 07:00:30' | System | 11 Mar 2021 13:00:35 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '11 Mar 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '15 Mar 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-03-18T16:24:08-05:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '30debd0f-11d0-498f-a2ca-dcd7c3c8497c' | System | 18 Mar 2021 21:24:20 |
| User entered 'No (N)' | System | 18 Mar 2021 21:24:20 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

Have you been exposed to someone with 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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-03-18T16:24:13-05:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '30debd0f-11d0-498f-a2ca-dcd7c3c8497c' | System | 18 Mar 2021 21:24:20 |
| User entered 'No (N)' | System | 18 Mar 2021 21:24:20 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-03-18T16:24:17-05:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '30debd0f-11d0-498f-a2ca-dcd7c3c8497c' User entered '18 Mar 2021 16:24:17' | System | 18 Mar 2021 21:24:20 |
| | System | 18 Mar 2021 21:24:20 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '18 Mar 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '22 Mar 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-03-25T14:37:10-05:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '8f0cf387-c541-4d27-b2e1-4d636057d725' | System | 25 Mar 2021 19:37:21 |
| User entered 'No (N)' | System | 25 Mar 2021 19:37:21 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Have you been exposed to someone with 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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-03-25T14:37:13-05:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '8f0cf387-c541-4d27-b2e1-4d636057d725' | System | 25 Mar 2021 19:37:21 |
| User entered 'No (N)' | System | 25 Mar 2021 19:37:21 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-03-25T14:37:16-05:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '8f0cf387-c541-4d27-b2e1-4d636057d725' User entered '25 Mar 2021 14:37:16' | System | 25 Mar 2021 19:37:21 |
| | System | 25 Mar 2021 19:37:21 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '25 Mar 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '29 Mar 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-04-03T08:05:54-05:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '49ed7b3a-6dab-44c0-8131-738c00db9d05' User entered 'No (N)' | System | 03 Apr 2021 13:06:05 |
| | System | 03 Apr 2021 13:06:05 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

Have you been exposed to someone with 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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-04-03T08:05:58-05:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '49ed7b3a-6dab-44c0-8131-738c00db9d05' | System | 03 Apr 2021 13:06:05 |
| User entered 'No (N)' | System | 03 Apr 2021 13:06:05 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-04-03T08:06:01-05:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '49ed7b3a-6dab-44c0-8131-738c00db9d05' | System | 03 Apr 2021 13:06:05 |
| User entered '03 Apr 2021 08:06:01' | System | 03 Apr 2021 13:06:05 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '01 Apr 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '05 Apr 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-04-09T14:36:20-05:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '5f489d62-b598-49c9-85bf-1de0053fc6ff' User entered 'No (N)' | System | 09 Apr 2021 19:36:37 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

Have you been exposed to someone with 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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-04-09T14:36:24-05:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '5f489d62-b598-49c9-85bf-1de0053fc6ff' User entered 'No (N)' | System | 09 Apr 2021 19:36:37 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-04-09T14:36:29-05:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '5f489d62-b598-49c9-85bf-1de0053fc6ff' User entered '09 Apr 2021 14:36:29' | System | 09 Apr 2021 19:36:37 |
| | System | 09 Apr 2021 19:36:37 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '08 Apr 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '12 Apr 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-04-18T08:47:28-05:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '09131060-ec24-4127-8dd9-30e59da1fd1a' User entered 'No (N)' | System | 18 Apr 2021 13:47:48 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

Have you been exposed to someone with 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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-04-18T08:47:42-05:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '09131060-ec24-4127-8dd9-30e59da1fd1a' | System | 18 Apr 2021 13:47:48 |
| User entered 'No (N)' | System | 18 Apr 2021 13:47:48 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-04-18T08:47:45-05:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '09131060-ec24-4127-8dd9-30e59da1fd1a' | System | 18 Apr 2021 13:47:48 |
| User entered '18 Apr 2021 08:47:45' | System | 18 Apr 2021 13:47:48 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '15 Apr 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '19 Apr 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-04-22T13:21:18-05:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '1bc5fa28-6285-4023-b0d4-11a5e21a437e' User entered 'No (N)' | System | 22 Apr 2021 18:21:38 |
| | System | 22 Apr 2021 18:21:38 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

Have you been exposed to someone with 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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-04-22T13:21:28-05:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '1bc5fa28-6285-4023-b0d4-11a5e21a437e' User entered 'No (N)' | System | 22 Apr 2021 18:21:38 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-04-22T13:21:31-05:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '1bc5fa28-6285-4023-b0d4-11a5e21a437e' User entered '22 Apr 2021 13:21:31' | System | 22 Apr 2021 18:21:38 |
| | System | 22 Apr 2021 18:21:38 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '22 Apr 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '26 Apr 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-04-29T08:19:20-05:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'a5b20211-9d4c-4c37-8522-018b199cb6cc' User entered 'No (N)' | System | 29 Apr 2021 13:19:48 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Have you been exposed to someone with 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 (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-04-29T08:19:25-05:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'a5b20211-9d4c-4c37-8522-018b199cb6cc' User entered 'No (N)' | System | 29 Apr 2021 13:19:48 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-04-29T08:19:29-05:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: 'a5b20211-9d4c-4c37-8522-018b199cb6cc' User entered '29 Apr 2021 08:19:29' | System | 29 Apr 2021 13:19:48 |
| | System | 29 Apr 2021 13:19:48 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '29 Apr 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '03 May 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '06 May 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '10 May 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '13 May 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '17 May 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '20 May 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '24 May 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '27 May 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '31 May 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '03 Jun 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '07 Jun 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '10 Jun 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '14 Jun 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '17 Jun 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '21 Jun 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '24 Jun 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '28 Jun 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '01 Jul 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '05 Jul 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '08 Jul 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '12 Jul 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '15 Jul 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '19 Jul 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '22 Jul 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '26 Jul 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '29 Jul 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '02 Aug 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '05 Aug 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '09 Aug 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '12 Aug 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '16 Aug 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '19 Aug 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '23 Aug 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '26 Aug 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '30 Aug 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '02 Sep 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '06 Sep 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '09 Sep 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '13 Sep 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '16 Sep 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '20 Sep 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '23 Sep 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '27 Sep 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '30 Sep 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '04 Oct 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '07 Oct 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '11 Oct 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '14 Oct 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '18 Oct 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '21 Oct 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '25 Oct 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '28 Oct 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '01 Nov 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '04 Nov 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '08 Nov 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '11 Nov 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '15 Nov 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '18 Nov 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '22 Nov 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '25 Nov 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '29 Nov 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '02 Dec 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '06 Dec 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '09 Dec 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '13 Dec 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '16 Dec 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '20 Dec 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '23 Dec 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '27 Dec 2021 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '30 Dec 2021 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '03 Jan 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '06 Jan 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '10 Jan 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '13 Jan 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '17 Jan 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '20 Jan 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '24 Jan 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '27 Jan 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '31 Jan 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '03 Feb 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '07 Feb 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '10 Feb 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '14 Feb 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '17 Feb 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '21 Feb 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '24 Feb 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '28 Feb 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '03 Mar 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '07 Mar 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '10 Mar 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '14 Mar 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '17 Mar 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '21 Mar 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '24 Mar 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '28 Mar 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '31 Mar 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '04 Apr 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '07 Apr 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '11 Apr 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '14 Apr 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '18 Apr 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '21 Apr 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '25 Apr 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '28 Apr 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '02 May 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '05 May 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '09 May 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '12 May 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '16 May 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '19 May 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '23 May 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '26 May 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '30 May 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '02 Jun 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '06 Jun 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '09 Jun 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '13 Jun 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '16 Jun 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '20 Jun 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '23 Jun 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '27 Jun 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '30 Jun 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '04 Jul 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '07 Jul 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '11 Jul 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '14 Jul 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '18 Jul 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '21 Jul 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '25 Jul 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '28 Jul 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '01 Aug 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '04 Aug 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '08 Aug 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '11 Aug 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '15 Aug 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '18 Aug 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '22 Aug 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '25 Aug 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '29 Aug 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '01 Sep 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '05 Sep 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '08 Sep 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '12 Sep 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '15 Sep 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '19 Sep 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '22 Sep 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '26 Sep 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '29 Sep 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '03 Oct 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '06 Oct 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '10 Oct 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '13 Oct 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '17 Oct 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '20 Oct 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '24 Oct 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '27 Oct 2022 00:01' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:38:09 |
| Amendment Manager: User entered '31 Oct 2022 23:59' | System | 19 Nov 2020 17:38:09 |

US3292312

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:30:59

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:06:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-03-01T10:01:51-06:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '69eccc2c-1d62-4bff-b0a8-5455053b24e7' | System | 01 Mar 2021 16:02:06 |
| User entered 'No (N)' | System | 01 Mar 2021 16:02:06 |

US3292312

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:30:59

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:06:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DAA85EBB-5510-44E3-B0F7-ED5978488F78)', Time: '2021-03-01T10:02:01-06:00', User OID: 'PatientReportedOutcome (US3292312)', ODM File OID: '69eccc2c-1d62-4bff-b0a8-5455053b24e7' User entered '01 Mar 2021 10:02:01' | System | 01 Mar 2021 16:02:06 |
| | System | 01 Mar 2021 16:02:06 |

US3292312

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| DataPoint Verified. | | 16 Mar 2021 13:56:44 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'Yes (Y)' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 19 Nov 2020 19:10:38 |

US3292312

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| DataPoint Verified. | | 16 Mar 2021 13:56:44 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered '17 Nov 2020' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 19 Nov 2020 19:10:38 |

US3292312

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| DataPoint Verified. | | 16 Mar 2021 13:56:44 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 19 Nov 2020 19:10:38 |

US3292312

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| DataPoint Verified. | | 16 Mar 2021 13:56:44 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered empty. | (b) (4) Gerardo Pena (b) (4) (b) (4) | 19 Nov 2020 19:10:38 |

US3292312

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| DataPoint Verified. | (b) (4) | 16 Mar 2021 13:57:39 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:11:03 |
| User entered 'Yes (Y)' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 19 Nov 2020 19:10:45 |

US3292312

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:13 |
| User entered 'l' | System | 19 Nov 2020 19:10:45 |

US3292312

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:50:22 |
| DataPoint Verified. | | 16 Mar 2021 13:57:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 23 Dec 2020 14:53:30 |

US3292312

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:50:22 |
| DataPoint Verified. | | 16 Mar 2021 13:57:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '21 Dec 2020' | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 14:53:30 |

US3292312

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:50:22 |
| DataPoint Verified. | (b) (4) | 16 Mar 2021 13:57:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 23 Dec 2020 14:53:30 |

US3292312

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:50:22 |
| DataPoint Verified. | | 16 Mar 2021 13:57:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4), (b) (6) | 23 Dec 2020 14:53:30 |

US3292312

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:50:22 |
| DataPoint Verified. | | 16 Mar 2021 13:58:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 23 Dec 2020 14:54:21 |

US3292312

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:50:22 |
| User entered 'l' | System | 23 Dec 2020 14:54:21 |

US3292312

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:50:22 |
| DataPoint Verified. | | 16 Mar 2021 13:58:48 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 26 Jan 2021 16:40:08 |

US3292312

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:50:22 |
| DataPoint Verified. | | 16 Mar 2021 13:58:48 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '20 Jan 2021' | (b) (4) (b) (4), (b) (6) | 26 Jan 2021 16:40:08 |

US3292312

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:50:22 |
| DataPoint Verified. | | 16 Mar 2021 13:58:48 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 26 Jan 2021 16:40:08 |

US3292312

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:50:22 |
| DataPoint Verified. | | 16 Mar 2021 13:58:48 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 26 Jan 2021 16:40:08 |

US3292312

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:50:22 |
| DataPoint Verified. | | 16 Mar 2021 13:59:51 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Jan 2021 16:42:13 |

US3292312

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:50:22 |
| User entered 'l' | System | 26 Jan 2021 16:42:13 |

US3292312

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:50:27 |
| DataPoint Verified. | | 16 Mar 2021 14:00:55 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 18:42:19 |
| User entered 'Yes (Y)' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 23 Feb 2021 15:23:11 |

US3292312

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:50:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Mar 2021 14:00:55 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 18:42:19 |
| User entered '22 Feb 2021' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 23 Feb 2021 15:23:11 |

US3292312

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:50:27 |
| DataPoint Verified. | | 16 Mar 2021 14:00:55 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 18:42:19 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 23 Feb 2021 15:23:11 |

US3292312

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:50:27 |
| DataPoint Verified. | | 16 Mar 2021 14:00:55 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 18:42:19 |
| User entered empty. | (b) (4) Gerardo Pena (b) (4) (b) (4) | 23 Feb 2021 15:23:11 |

US3292312

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:50:27 |
| DataPoint Verified. | | 16 Mar 2021 14:01:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 18:42:19 |
| User entered 'Yes (Y)' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 23 Feb 2021 15:23:16 |

US3292312

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:50:27 |
| User entered 'l' | System | 23 Feb 2021 15:23:16 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:30:59

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 16:37:01 |
| User entered 'Yes (Y)' | | 20 Mar 2021 17:06:04 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 16:37:01 |
| User entered '19 Mar 2021' | | 20 Mar 2021 17:06:04 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 16:37:01 |
| User entered 'Clinic (Clinic)' | | 20 Mar 2021 17:06:04 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:30:59

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'VISIT4' | System | 20 Mar 2021 17:06:04 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 16:37:22 |
| User entered 'No (N)' | | 31 Mar 2021 19:26:50 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 16:37:22 |
| User entered empty. | | 31 Mar 2021 19:26:50 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 16:37:22 |
| User entered empty. | | 31 Mar 2021 19:26:50 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered empty. | System | 31 Mar 2021 19:26:50 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 16:37:22 |
| User entered empty. | | 31 Mar 2021 19:26:50 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 16:37:22 |
| User entered empty. | | 31 Mar 2021 19:26:50 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 16:37:22 |
| User entered empty. | | 31 Mar 2021 19:26:50 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 16:37:22 |
| User entered empty. | | 31 Mar 2021 19:26:50 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered empty. | System | 31 Mar 2021 19:26:50 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 16:37:22 |
| User entered empty. | | 31 Mar 2021 19:26:50 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered empty. | System | 31 Mar 2021 19:26:50 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 16:37:22 |
| User entered empty. | | 31 Mar 2021 19:26:50 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered empty. | System | 31 Mar 2021 19:26:50 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 16:37:22 |
| User entered empty. | | 31 Mar 2021 19:26:50 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered empty. | System | 31 Mar 2021 19:26:50 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:59

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:30:59

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 16:37:47 |
| User entered 'No (N)' | | 20 Mar 2021 17:06:09 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:30:59

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 16:37:47 |
| User entered empty. | | 20 Mar 2021 17:06:09 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:30:59

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 16:37:28 |
| User entered 'Yes (Y)' | | 20 Mar 2021 17:06:41 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:30:59

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) | 08 Apr 2021 16:37:28 |
| User entered '19 Mar 2021' | (b) (4), (b) (6) | 20 Mar 2021 17:06:41 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:30:59

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 16:37:28 |
| User entered '14:10' | | 20 Mar 2021 17:06:41 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:30:59

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered '19 Mar 2021 14:10' | System | 20 Mar 2021 17:06:41 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 08 Apr 2021 16:38:00 |
| User entered 'Yes (Y)' | | 20 Mar 2021 17:06:45 |

US3292312

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:22:40 |
| User entered 'I' | System | 20 Mar 2021 17:06:45 |

US3292312

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:34:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 23 Apr 2021 14:04:29 |

US3292312

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:34:44 |
| User entered '23 Apr 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 23 Apr 2021 14:38:49 |
| User entered '21 Apr 2021' | | 23 Apr 2021 14:04:29 |

US3292312

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:34:44 |
| User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error | (b) (4) | 23 Apr 2021 14:38:49 |
| User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error | (b) (4), (b) (6) | 23 Apr 2021 14:23:13 |
| User entered 'Contact Made (CONTACT MADE)' | | 23 Apr 2021 14:04:29 |

US3292312

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:59

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:34:44 |
| User entered empty; reason for change Data Entry Error | (b) (4) | 23 Apr 2021 14:38:49 |
| User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. | (b) (4), (b) (6) | 23 Apr 2021 14:23:25 |
| Please review and reconcile.' (Site from System). | | |
| User entered '3 attempts no answer' reason for change: Data Entry Error | (b) (4), (b) (6) | 23 Apr 2021 14:23:25 |
| User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. | System | 23 Apr 2021 14:23:13 |
| Please review and reconcile.' (Site from System). | | |
| User entered empty. | (b) (4), (b) (6) | 23 Apr 2021 14:04:29 |

US3292312

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:34:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 23 Apr 2021 14:04:33 |

US3292312

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 23 Apr 2021 14:04:33 |

US3292312

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

Form: Visit Date

Generated On: 09 Jun 2021 16:30:59

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:28:54 |
| DataPoint Verified. | | 16 Apr 2021 18:17:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'Yes (Y)' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:13:24 |

US3292312

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

Form: Visit Date

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:28:54 |
| DataPoint Verified. | | 16 Apr 2021 18:17:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered '4 Mar 2021' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:13:24 |

US3292312

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

Form: Visit Date

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|--------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:28:54 |
| DataPoint Verified. | | 16 Apr 2021 18:17:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'Clinic (Clinic)' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:13:24 |

US3292312

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

Form: Visit Date

Generated On: 09 Jun 2021 16:30:59

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:28:54 |
| User entered 'UNBLND_DECIDE' | System | 05 Mar 2021 15:13:24 |

US3292312

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

Form: Unblinding

Generated On: 09 Jun 2021 16:30:59

Date of updated informed consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:28:54 |
| DataPoint Verified. | | 16 Apr 2021 18:17:43 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered '4 Mar 2021' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:13:44 |

US3292312

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

Form: Unblinding

Generated On: 09 Jun 2021 16:30:59

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:28:54 |
| DataPoint Verified. | (b) (4) | 23 Apr 2021 19:07:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:34:44 |
| User entered '0' | (b) (4) Dawn Killian (b) (4) | 23 Apr 2021 07:37:39 |
| Amendment Manager inserted this DataPoint. | (b) (4) System | 06 Mar 2021 06:43:56 |

US3292312

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

Form: Unblinding

Generated On: 09 Jun 2021 16:30:59

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:28:54 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:17:43 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'Yes (Y)' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:13:44 |

US3292312

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

Form: Unblinding

Generated On: 09 Jun 2021 16:30:59

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:28:54 |
| User closed query 'Per sponsor review, 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). | | 26 Apr 2021 15:01:06 |
| DataPoint Verified. | | 23 Apr 2021 19:07:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:34:44 |
| Query 'Per sponsor review, 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). | (b) (4) Dawn Killian (b) (4) (b) (4) | 23 Apr 2021 07:37:45 |
| User entered 'Amendment 6 or later (Amendment 6 or later)' | Dawn Killian (b) (4) (b) (4) | 23 Apr 2021 07:37:39 |
| User opened query 'Per sponsor review, 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 04:52:18 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 06:43:56 |

US3292312

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

Form: Unblinding

Generated On: 09 Jun 2021 16:30:59

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:28:54 |
| DataPoint Verified. | | 16 Apr 2021 18:17:43 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered '4 Mar 2021' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:13:44 |

US3292312

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

Form: Unblinding

Generated On: 09 Jun 2021 16:30:59

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|--------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:28:54 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:17:43 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:13:44 |

US3292312

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

Form: Unblinding

Generated On: 09 Jun 2021 16:30:59

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|--------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:28:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:17:43 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:13:44 |

US3292312

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

Form: Unblinding

Generated On: 09 Jun 2021 16:30:59

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|--------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:28:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:17:43 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:13:44 |

US3292312

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

Form: Unblinding

Generated On: 09 Jun 2021 16:30:59

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:28:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:17:43 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'No (N)' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:13:44 |

US3292312

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

Form: Unblinding

Generated On: 09 Jun 2021 16:30:59

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:28:54 |
| User entered empty. | System | 05 Mar 2021 15:13:44 |

US3292312

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

Form: Unblinding

Generated On: 09 Jun 2021 16:30:59

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:28:54 |
| User entered empty. | System | 05 Mar 2021 15:13:44 |

US3292312

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:30:59

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:28:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:17:50 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'Yes (Y)' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:14:08 |

US3292312

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:30:59

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:28:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:17:50 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered '4 Mar 2021' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:14:08 |

US3292312

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:30:59

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:28:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:17:50 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered '11:02' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:14:08 |

US3292312

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:30:59

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:28:54 |
| User entered '4 Mar 2021 11:02' | System | 05 Mar 2021 15:14:08 |

US3292312

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:30:59

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:28:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:17:55 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'Yes (Y)' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:14:19 |

US3292312

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:28:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:17:55 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered '4 Mar 2021' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:14:19 |

US3292312

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:30:59

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:28:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:17:55 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered '11:39' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:14:19 |

US3292312

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:30:59

[Collection Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:28:54 |
| User entered '4 Mar 2021 11:39' | System | 05 Mar 2021 15:14:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:30:59

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 05:13:31 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| User closed query 'Please Add Constipation AE to EDC' (Site from CRA). | (b) (4) | |
| Query 'Please Add Constipation AE to EDC' answered with 'added' (Site from CRA). | (b) (4), (b) (6) | 23 Mar 2021 17:49:09 |
| User opened query 'Please Add Constipation AE to EDC' (Site from CRA). | | 11 Feb 2021 15:53:23 |
| DataPoint Verified. | | 08 Feb 2021 18:12:02 |
| | | 04 Nov 2020 23:03:13 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:15:53 |

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

[AEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:05:58 |
| Reviewed for Safety. | (b) (4), (b) (6) | 27 Oct 2020 14:24:43 |
| User entered | System | 27 Oct 2020 14:24:29 |
| 'USA-US072-2020-mRNA-1273-P301000006' | | |
| User entered 'New' | (b) (4), (b) (6) | 27 Oct 2020 14:24:29 |

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Stroke - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 26 Oct 2020 19:47:20 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 26 Oct 2020 19:47:20 |
| Data point term sent to Coder | System | 26 Oct 2020 19:35:33 |
| User entered 'Stroke' | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| User entered '25 Oct 2020' | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| User entered empty. | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Oct 2020 19:35:20 |

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 18 Jan 2021 19:41:13 |
| User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). | System | 24 Nov 2020 23:43:25 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 24 Nov 2020 23:43:25 |
| User entered 'No (N)' reason for change: Per Query Resolution | | 24 Nov 2020 23:43:25 |
| User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). | System | 24 Nov 2020 23:42:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 18 Jan 2021 19:41:00 |
| User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | | 12 Jan 2021 08:47:24 |
| Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'updated' (Site from System). | Victoria Hernandez (b) (4) | 11 Jan 2021 20:29:36 |
| User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | (b) (4), (b) (6) | 25 Nov 2020 19:58:51 |
| Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'UPDATED' (Site from Safety). | | 24 Nov 2020 23:43:39 |
| User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | System | 24 Nov 2020 23:42:56 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 24 Nov 2020 23:42:56 |
| User entered '25 Oct 2020' reason for change: Per Query Resolution | | 24 Nov 2020 23:42:56 |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | | 16 Nov 2020 18:44:26 |
| User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | | 09 Nov 2020 16:42:37 |
| Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'NO END DATE AS OF 26OCT2020' (Site from Safety). | Victoria Hernandez (b) (4) | 06 Nov 2020 17:21:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty. | (b) (4), (b) (6) | 04 Nov 2020 20:43:54 |
| | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| User entered empty. | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Query 'PV Query: Please confirm event end date as the outcome if provided as recovering/resolving.' canceled (Site from Safety). | (b) (4), (b) (6) | 08 Feb 2021 02:41:11 |
| User opened query 'PV Query: Please confirm event end date as the outcome if provided as recovering/resolving.' (Site from Safety). | | 04 Dec 2020 13:50:31 |
| User entered empty. | System | 26 Oct 2020 19:35:20 |

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

[Severity](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| User entered 'Grade 4 (Grade 4)' | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| User entered '0' | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| User entered '0' | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:05:58 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | (b) (4), (b) (6) | 03 Nov 2020 12:54:37 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Patient is still hospitalized, no discharge date available' (Site from System). | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:38:07 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | System | 26 Oct 2020 19:35:20 |
| User entered 'I' | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| User entered '25 Oct 2020' | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| User closed query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved.' (Site from Safety). | (b) (4) | |
| Query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved.' answered with 'per med recs subject was required to remain hospitalized for results from echo, and CT scan.' (Site from Safety). | (b) (4), (b) (6) | 08 Feb 2021 14:34:39 |
| User opened query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved.' | Victoria Hernandez (b) (4) | 05 Feb 2021 18:57:28 |
| DataPoint Verified. | (b) (4) | |
| User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety). | (b) (4), (b) (6) | 21 Jan 2021 15:23:49 |
| Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'UPDATED' (Site from Safety). | | 18 Jan 2021 19:41:07 |
| DataPoint Un-verified. | | 25 Nov 2020 19:58:45 |
| User entered '29 Oct 2020' reason for change: Per Query Resolution | | 24 Nov 2020 23:41:00 |
| User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety). | | 24 Nov 2020 23:40:48 |
| User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety). | | 24 Nov 2020 23:40:48 |
| Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'SUBJECT IS STILL IN HOSPITAL AS OF 26OCT2020' (Site from Safety). | | 16 Nov 2020 18:44:07 |
| DataPoint Verified. | | 09 Nov 2020 16:42:40 |
| User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety). | Victoria Hernandez (b) (4) | 06 Nov 2020 17:21:25 |
| User entered empty. | (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| | | 04 Nov 2020 20:43:39 |
| | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| User entered '2' | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

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Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| User entered '0' | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

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[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| User entered '0' | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

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[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| User entered '0' | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

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[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| User entered 'Not Related (NOT RELATED)' | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

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[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| User entered 'Not Related (NOT RELATED)' | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

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[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

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Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

None

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | (b) (4) System | 11 Feb 2021 15:28:52 |
| User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System | 09 Feb 2021 21:07:35 |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| User entered '0' | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 31 Mar 2021 21:01:57 |
| User closed query 'Per CDM: Please kindly mention the CM# logline number that corresponds to the Stroke Indication, Else clarify.' (Site from DM). | | 25 Mar 2021 09:44:06 |
| Query 'Per CDM: Please kindly mention the CM# logline number that corresponds to the Stroke Indication, Else clarify.' answered with 'CONMED LOG UPDATED' (Site from DM). | Antonio Gutierrez (b) (4) | 24 Mar 2021 20:11:32 |
| User opened query 'Per CDM: Please kindly mention the CM# logline number that corresponds to the Stroke Indication, Else clarify.' (Site from DM). | (b) (4), (b) (6) | 24 Mar 2021 11:05:51 |
| User closed query 'Per CDM: Other action taken is Concomitant Medication however, there is no corresponding Concomitant Medication record(s) for 'STROKE'. Please review and reconcile accordingly.' (Site from DM). | | 24 Mar 2021 11:05:51 |
| Query 'Per CDM: Other action taken is Concomitant Medication however, there is no corresponding Concomitant Medication record(s) for 'STROKE'. Please review and reconcile accordingly.' answered with 'yes there is' (Site from DM). | Dawn Killian (b) (4) | 23 Mar 2021 19:13:26 |
| | (b) (4) | |
| User opened query 'Per CDM: Other action taken is Concomitant Medication however, there is no corresponding Concomitant Medication record(s) for 'STROKE'. Please review and reconcile accordingly.' (Site from DM). | (b) (4), (b) (6) | 12 Feb 2021 10:22:54 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 11 Feb 2021 15:59:09 |
| User entered '1' reason for change: Per Query Resolution | | 11 Feb 2021 15:59:09 |
| DataPoint Verified. | | 04 Nov 2020 23:05:58 |
| User entered '0' | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |
| | (b) (4) | |

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[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 31 Mar 2021 21:01:57 |
| User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM). | | 12 Feb 2021 10:23:00 |
| User entered '0' reason for change: Data Entry Error | | 11 Feb 2021 15:59:09 |
| Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'procedures added' (Site from DM). | | 11 Feb 2021 15:29:11 |
| User entered '1' reason for change: Data Entry Error | | 11 Feb 2021 15:28:52 |
| DataPoint Un-verified. | Victoria Hernandez (b) (4) | 09 Feb 2021 21:07:35 |
| User entered '0' reason for change: Data Entry Error | (b) (4) | |
| | Victoria Hernandez (b) (4) | 09 Feb 2021 21:07:35 |
| User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM). | (b) (4) | |
| | (b) (4), (b) (6) | 23 Nov 2020 23:40:46 |
| User closed query 'Per CDM: Concomitant Procedures check box "checked" however concomitant Procedures eCRF has not been updated? Please review and update accordingly.' (Site from DM). | | 23 Nov 2020 15:37:14 |
| Query 'Per CDM: Concomitant Procedures check box "checked" however concomitant Procedures eCRF has not been updated? Please review and update accordingly.' answered with 'UPDATED' (Site from DM). | Victoria Hernandez (b) (4) | 06 Nov 2020 17:24:20 |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |

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[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User opened query 'Per CDM: Concomitant Procedures check box "checked" however concomitant Procedures eCRF has not been updated? Please review and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 30 Oct 2020 10:48:15 |
| User entered 'I' | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

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[Outcome](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 18 Jan 2021 19:41:13 |
| User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4), (b) (6) | 15 Jan 2021 14:19:02 |
| User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date (25-OCT-2020) is provided. Please correct.' (Site from DM). | | 14 Jan 2021 10:15:17 |
| Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date (25-OCT-2020) is provided. Please correct.' answered with 'corrected' (Site from DM). | | 13 Jan 2021 22:12:45 |
| Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'provided' (Site from Safety). | | 13 Jan 2021 22:12:35 |
| DataPoint Un-verified. | | 13 Jan 2021 22:10:58 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | | 13 Jan 2021 22:10:58 |
| User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date (25-OCT-2020) is provided. Please correct.' (Site from DM). | | 12 Jan 2021 08:48:36 |
| User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | | 16 Nov 2020 18:44:43 |
| User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | | 09 Nov 2020 16:42:44 |

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[Outcome](#)

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'AS OF 26OCT2020 SUBJECT IS STILL IN ICU' (Site from Safety). DataPoint Verified. | Victoria Hernandez (b) (4) | 06 Nov 2020 17:24:41 |
| | (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | | 04 Nov 2020 20:44:27 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| User entered empty. | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

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[Narrative](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User opened query 'PV query: Please consider whether acute on chronic systolic and diastolic dysfunction, present on admission meets the reporting criteria for AE/SAE, and update report if appropriate. | (b) (4), (b) (6) | 03 May 2021 17:13:41 |
| ' (Site from Safety). | | |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| User closed query 'PV Query: Please provide lab units and reference ranges if available. ' (Site from Safety). | (b) (4) | |
| User closed query 'PV query: Please consider whether acute on chronic systolic and diastolic dysfunction , present on admission meets the reporting criteria for AE/SAE, and update report if appropriate.' (Site from Safety). | (b) (4), (b) (6) | 22 Apr 2021 15:11:51 |
| User closed query 'PV Query: Please provide results of head CT performed on 26 Oct 2020. If unknown, please indicate so. ' (Site from Safety). | | 22 Apr 2021 15:11:47 |
| User closed query 'PV Query: Please confirm date of ECHO. If unknown, please indicate so. ' (Site from Safety). | | 22 Apr 2021 15:11:44 |
| Query 'PV Query: Please provide lab units and reference ranges if available. ' answered with 'Relevant records pages sent to Safety inbox' (Site from Safety). | Nathan Cortez (b) (4) | 21 Apr 2021 20:12:42 |
| Query 'PV query: Please consider whether acute on chronic systolic and diastolic dysfunction , present on admission meets the reporting criteria for AE/SAE, and update report if appropriate.' answered with 'To be added as AE' (Site from Safety). | Nathan Cortez (b) (4) | 21 Apr 2021 20:01:20 |
| Query 'PV Query: Please provide results of head CT performed on 26 Oct 2020. If unknown, please indicate so. ' answered with 'Impression: "No CT evidence of an acute intracranial abnormality. Stable cerebrovascular atherosclerosis.' (Site from Safety). | Nathan Cortez (b) (4) | 21 Apr 2021 18:23:15 |
| Query 'PV Query: Please confirm date of ECHO. If unknown, please indicate so. ' answered with 'Last Echo 2/19/19 per records, prior to study.' (Site from Safety). | Nathan Cortez (b) (4) | 21 Apr 2021 18:16:08 |

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| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User opened query 'PV Query: Please provide lab units and reference ranges if available. ' (Site from Safety). | (b) (4), (b) (6) | 02 Apr 2021 02:11:51 |
| User opened query 'PV query: Please consider whether acute on chronic systolic and diastolic dysfunction , present on admission meets the reporting criteria for AE/SAE, and update report if appropriate.' (Site from Safety). | (b) (4), (b) (6) | 02 Apr 2021 02:11:42 |
| Query 'query: Please consider whether acute on chronic systolic and diastolic dysfunction , present on admission meets the reporting criteria for AE/SAE, and update report if appropriate.' canceled (Site from Safety). | (b) (4), (b) (6) | 02 Apr 2021 02:11:34 |
| User opened query 'query: Please consider whether acute on chronic systolic and diastolic dysfunction , present on admission meets the reporting criteria for AE/SAE, and update report if appropriate.' (Site from Safety). | (b) (4), (b) (6) | 02 Apr 2021 02:11:29 |
| User opened query 'PV Query: Please provide results of head CT performed on 26 Oct 2020. If unknown, please indicate so. ' (Site from Safety). | (b) (4), (b) (6) | 02 Apr 2021 02:11:17 |
| User opened query 'PV Query: Please confirm date of ECHO. If unknown, please indicate so. ' (Site from Safety). | (b) (4), (b) (6) | 02 Apr 2021 02:11:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 21:01:57 |
| User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6) | 25 Mar 2021 13:06:29 |
| 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) | 25 Mar 2021 13:06:25 |

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| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results, including the CT scan and MRI (and follow-up CT, MRI if performed). Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 25 Mar 2021 13:06:21 |
| User closed query 'PV Query: Please confirm if the subject had an echocardiogram and provide the results. If not performed, please state so in your response.' (Site from Safety). | | 25 Mar 2021 13:06:19 |
| User closed query 'Per CDM: Per previous query response "blood thinner added"; however, the update is not obvious please provide location of update such as log line number. Thank you.' (Site from DM). | | 25 Mar 2021 09:47:05 |
| User closed query 'Per CDM: Per previous query response "blood thinners added"; however, the update is not obvious please provide location of update such as log line number. Thank you.' (Site from DM). | | 25 Mar 2021 09:46:58 |
| Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Medications listed in ConMed log. No surgical interventions. Discharge summary sent to Safety email address provided.' (Site from Safety). | Antonio Gutierrez (b) (4) | 24 Mar 2021 20:15:10 |
| 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 'Emailed @ 2:47pm Central on 24MAR2021.' (Site from Safety). | Antonio Gutierrez (b) (4) | 24 Mar 2021 19:48:00 |

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| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results, including the CT scan and MRI (and follow-up CT, MRI if performed). Please include units and reference ranges if applicable.' answered with 'TEE: degenerative calcific aortic valve disease with no evidence of vegetation (less likely) with mild thickening and mild to moderate aortic stenosis. Small PFO is present with R to L shunt. No evidence of left atrial or left atrial appendage thrombus. mild atheromatous plaque in ascending aorta, descending distal aortic arch, and proximal descending aorta. low normal to mildly reduced LV systolic function with mild MR. CTA Head and Neck: mild intracranial atherosclerosis without evidence of large vessel cut off. no intracranial aneurysm or vascular malformation, right carotid bifurcation atherosclerosis with 71% stenosis. left carotid bifurcation atherosclerosis with 51% stenosis just beyond the carotid bulb. patent bilateral vertebral arteries. MRI of Brain w/o contrast: bilateral acute cerebellar infarcts. punctate small parafalcine infarct within the right occipital lobe measuring 4mm. Carotid DOP: velocity criteria extrapolated from diameter data indicates severe stenosis of the right internal carotid in excess of 70% diameter reduction. approximately 50% diameter reduction left internal carotid. flow reversal left vertebral artery suggesting proximal stenosis left subclavian artery. Chest radiograph: No focal consolidation in the lungs. Prior sternotomy. ' (Site from Safety). | Antonio Gutierrez (b) (4) | 24 Mar 2021 19:39:09 |
| Query 'Per CDM: Per previous query response "blood thinners added"; however, the update is not obvious please provide location of update such as log line number. Thank you. ' answered with 'Patient received Alteplase/Activase at admission, but further information (dose, units, route, etc) was not provided and not available. ' (Site from DM). | Antonio Gutierrez (b) (4) | 24 Mar 2021 19:02:18 |

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[Narrative](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| Query 'PV Query: Please confirm if the subject had an echocardiogram and provide the results. If not performed, please state so in your response.' | Antonio Gutierrez (b) (4) | 24 Mar 2021 18:48:30 |
| answered with 'Echocardiogram was done. Echo was concerning for infective endocarditis therefore TEE was done. No evidence of vegetation and small PFO present with right to left shunt on the TEE. No plans to fix PFO at this time. ' (Site from Safety). | | |
| DataPoint Un-verified. | Antonio Gutierrez (b) (4) | 24 Mar 2021 18:48:13 |
| | | |

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| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| User entered 'PATIENT CONTACTED STAFF ON 26OCT2020 TO STATE THAT HE HAD BEEN HOSPITALIZED IN THE ICU DUE TO A STROKE THAT OCCURRED ON 25OCT2020. ACCORDING TO THE PATIENT, HE HAD BEEN AT WORK ON THE AFTERNOON OF 25OCT2020 WHEN HE STARTED TO EXPERIENCE LIGHTHEADEDNESS AND BLURRY VISION. PATIENT STATES THAT HE SAT DOWN AND WAITED ABOUT 10 MINUTES BEFORE HE DECIDED TO CALL HIS WIFE TO PICK HIM UP FROM WORK TO TAKE HIM TO THE HOSPITAL. WHILE WAITING FOR HIS WIFE TO PICK HIM UP, PATIENT STATES THAT HE WAS TALKING WITH A COWORKER WHO NOTICED THAT HIS LEFT EYE BEGAN TO DRIFT LEFT, WHILE HIS RIGHT EYE REMAINED STATIONARY. UPON ARRIVAL TO THE ER, PATIENT STATES DOCTORS ORDERED A CT SCAN WHICH SHOWED EVIDENCE OF A STROKE. HOWEVER, PATIENT WAS UNABLE TO PROVIDE ANY INFORMATION AS TO WHERE THE STROKE ORIGINATED OR ITS SEVERITY. PATIENT ALSO STATES THAT HE WAS GIVEN AN echocardiogram. IN REGARDS TO MEDICATION, PATIENT STATES THAT HE WAS GIVEN AN UNKNOWN BLOOD THINNER, WHICH HE ATTRIBUTES TO FEELING BETTER AND RESTORING HIS VISION. AS OF TODAY, 26OCT2020, PATIENT IS STILL IN ICU AWAITING A FOLLOW-UP MRI AND CT SCAN. NO FURTHER INFORMATION IS AVAILABLE AT THIS TIME. MEDICAL RECORDS WILL BE REQUESTED AS SOON AS POSSIBLE. UPDATE 27OCT2020: PATIENT STATES HE WAS MOVED OUT OF ICU TODAY. NEUROLOGIST EXPLAINED TO PATIENT THAT THE STROKE SEEMS TO HAVE TAKEN PLACE IN THE RIGHT SIDE OF THE OCCIPITAL LOBE, WITH NO FURTHER | Antonio Gutierrez (b) (4) | 24 Mar 2021 18:48:13 |

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| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| INFORMATION AVAILABLE AT THIS TIME. FOLLOW-UP MRI AND CT SCAN INFORMATION NOT YET AVAILABLE, AS PATIENT IS TO MEET WITH NEUROLOGIST TO DISCUSS. PATIENT ALSO STATES THAT HIS HEART WENT INTO ATRIAL FIBRILLATION ON SUNDAY, 25OCT2020, TWICE, SO A CARDIOLOGY CONSULT HAS BEEN REQUESTED. AS OF 27OCT2020, PATIENT STATES THAT HE HAS BEEN STARTED ON BLOOD THINNERS, BUT NAME OR TYPE IS UNKNOWN. PATIENT REMAINS HOSPITALIZED, THOUGH NOW OUT OF ICU.' | | |
| reason for change: New Information Query 'Per CDM: Per previous query response "blood thinner added"; however, the update is not obvious please provide location of update such as log line number. Thank you. ' answered with 'repeat query, will answer the original' (Site from DM). | Antonio Gutierrez (b) (4) | 24 Mar 2021 17:45:06 |
| 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) | 08 Mar 2021 17:16:57 |
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | | 08 Mar 2021 17:16:47 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results, including the CT scan and MRI (and follow-up CT, MRI if performed). Please include units and reference ranges if applicable.' (Site from Safety). | | 08 Mar 2021 17:16:37 |
| User opened query 'PV Query: Please confirm if the subject had an echocardiogram and provide the results. If not performed, please state so in your response.' (Site from Safety). | | 08 Mar 2021 17:16:28 |

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| 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) | 12 Feb 2021 14:25:26 |
| User closed query 'PV Query: Please confirm if the subject had an echocardiogram and provide the results. If not performed, please state so in your response.' (Site from Safety). | | 12 Feb 2021 14:25:01 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results, including the CT scan and MRI (and follow-up CT, MRI if performed). Please include units and reference ranges if applicable.' (Site from Safety). | | 12 Feb 2021 14:24:56 |
| User closed query 'PV Query: Please confirm if Atrial Fibrillation on 25 Oct 2020 meets criteria for separate AE/SAE reporting. If not, please state so in your response.' (Site from Safety). | | 12 Feb 2021 14:24:52 |
| 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). | | 12 Feb 2021 14:24:44 |
| User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | | 12 Feb 2021 14:24:39 |
| User opened query 'Per CDM: Per previous query response "blood thinner added"; however, the update is not obvious please provide location of update such as log line number. Thank you.' (Site from DM). | | 12 Feb 2021 10:24:01 |
| User closed query 'Per DM CLR: SAE Narrative = PATIENT STATES THAT HE WAS GIVEN AN UNKNOWN BLOOD THINNER. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM). | | 12 Feb 2021 10:24:01 |

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

[Narrative](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User opened query 'Per CDM: Per previous query response "blood thinners added"; however, the update is not obvious please provide location of update such as log line number. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 12 Feb 2021 10:23:47 |
| User closed query 'Per DM CLR: SAE Narrative = PATIENT STATES THAT HE HAS BEEN STARTED ON BLOOD THINNERS, BUT NAME OR TYPE IS UNKNOWN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM). | (b) (4), (b) (6) | 12 Feb 2021 10:23:47 |
| Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'conmed added' (Site from Safety). | | 11 Feb 2021 16:07:20 |
| 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 'COVID test negative per medical lab records' (Site from Safety). | | 11 Feb 2021 16:06:56 |
| Query 'PV Query: Please confirm if Atrial Fibrillation on 25 Oct 2020 meets criteria for separate AE/SAE reporting. If not, please state so in your response.' answered with 'Medical records faxed in' (Site from Safety). | | 11 Feb 2021 16:04:32 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results, including the CT scan and MRI (and follow-up CT, MRI if performed). Please include units and reference ranges if applicable.' answered with 'Procedures added to log and Medical records faxed in' (Site from Safety). | | 11 Feb 2021 16:01:58 |
| Query 'PV Query: Please confirm if the subject had an echocardiogram and provide the results. If not performed, please state so in your response.' answered with 'Medical records faxed in' (Site from Safety). | | 11 Feb 2021 16:01:39 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Medical records faxed in' (Site from Safety). | (b) (4), (b) (6) | 11 Feb 2021 16:01:33 |
| Query 'Per DM CLR: SAE Narrative = PATIENT STATES THAT HE WAS GIVEN AN UNKNOWN BLOOD THINNER. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'blood thinner added' (Site from DM). | (b) (4), (b) (6) | 11 Feb 2021 15:58:26 |
| Query 'Per DM CLR: SAE Narrative = PATIENT STATES THAT HE HAS BEEN STARTED ON BLOOD THINNERS, BUT NAME OR TYPE IS UNKNOWN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'blood thinners added' (Site from DM). | | 11 Feb 2021 15:58:16 |
| User opened query 'Per DM CLR: SAE Narrative = PATIENT STATES THAT HE HAS BEEN STARTED ON BLOOD THINNERS, BUT NAME OR TYPE IS UNKNOWN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM). | | 23 Nov 2020 23:42:29 |
| User opened query 'Per DM CLR: SAE Narrative = PATIENT STATES THAT HE WAS GIVEN AN UNKNOWN BLOOD THINNER. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM). | | 23 Nov 2020 23:42:01 |
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | | 16 Nov 2020 18:45:04 |

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

[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) | 16 Nov 2020 18:43:44 |
| User opened query 'PV Query: Please confirm if Atrial Fibrillation on 25 Oct 2020 meets criteria for separate AE/SAE reporting. If not, please state so in your response.' (Site from Safety). | | 16 Nov 2020 18:43:27 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results, including the CT scan and MRI (and follow-up CT, MRI if performed). Please include units and reference ranges if applicable.' (Site from Safety). | | 16 Nov 2020 18:43:08 |
| User opened query 'PV Query: Please confirm if the subject had an echocardiogram and provide the results. If not performed, please state so in your response.' (Site from Safety). | | 16 Nov 2020 18:42:48 |
| 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). | | 09 Nov 2020 16:43:09 |
| User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so' (Site from Safety). | | 09 Nov 2020 16:43:06 |
| User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety). | | 09 Nov 2020 16:43:05 |
| User closed query 'PV Query: Please confirm if Atrial Fibrillation on 25 Oct 2020 meets criteria for separate AE/SAE reporting. If not, please state so in your response.' (Site from Safety). | | 09 Nov 2020 16:42:51 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

[Narrative](#)

| Audit | User | Time (GMT) |
|--|----------------------------|------------------------------|
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results, including the CT scan and MRI (and follow-up CT, MRI if performed). Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 09 Nov 2020 16:42:49 |
| User closed query 'PV Query: Please confirm if the subject had an echocardiogram and provide the results. If not performed, please state so in your response.' (Site from Safety). | | 09 Nov 2020 16:42:47 |
| Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so' answered with 'UNKNOWN BLOO THINNER WAS GIVEN AT HOSPITAL , PER SUBJECT ' (Site from Safety). | Victoria Hernandez (b) (4) | (b) (4) 06 Nov 2020 17:28:05 |
| Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'HYPERTENSION' (Site from Safety). | Victoria Hernandez (b) (4) | (b) (4) 06 Nov 2020 17:27:26 |
| 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 'WILL PROVIDE WHEN SUBJECT IS DISCHARGED' (Site from Safety). | Victoria Hernandez (b) (4) | (b) (4) 06 Nov 2020 17:26:23 |
| Query 'PV Query: Please confirm if Atrial Fibrillation on 25 Oct 2020 meets criteria for separate AE/SAE reporting. If not, please state so in your response.' answered with 'SAME AE ' (Site from Safety). | Victoria Hernandez (b) (4) | (b) (4) 06 Nov 2020 17:25:38 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results, including the CT scan and MRI (and follow-up CT, MRI if performed). Please include units and reference ranges if applicable.' answered with 'WILL PROVIDE WHEN SUBJECT IS DISCHARGED' (Site from Safety). | Victoria Hernandez (b) (4) | (b) (4) 06 Nov 2020 17:25:12 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

[Narrative](#)

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Query 'PV Query: Please confirm if the subject had an echocardiogram and provide the results. If not performed, please state so in your response.' | Victoria Hernandez (b) (4) | 06 Nov 2020 17:24:58 |
| answered with 'WILL PROVIDE WHEN SUBJECT IS RELEASED' (Site from Safety). | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Nov 2020 23:05:58 |
| 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). | | 04 Nov 2020 20:44:52 |
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so' (Site from Safety). | | 04 Nov 2020 20:44:37 |
| User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety). | | 04 Nov 2020 20:44:07 |
| 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). | | 04 Nov 2020 20:43:29 |
| User opened query 'PV Query: Please confirm if Atrial Fibrillation on 25 Oct 2020 meets criteria for separate AE/SAE reporting. If not, please state so in your response.' (Site from Safety). | | 04 Nov 2020 20:43:00 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results, including the CT scan and MRI (and follow-up CT, MRI if performed). Please include units and reference ranges if applicable.' (Site from Safety). | | 04 Nov 2020 20:42:51 |
| User opened query 'PV Query: Please confirm if the subject had an echocardiogram and provide the results. If not performed, please state so in your response.' (Site from Safety). | | 04 Nov 2020 20:42:43 |

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User entered 'PATIENT CONTACTED STAFF ON 26OCT2020 TO STATE THAT HE HAD BEEN HOSPITALIZED IN THE ICU DUE TO A STROKE THAT OCCURRED ON 25OCT2020. ACCORDING TO THE PATIENT, HE HAD BEEN AT WORK ON THE AFTERNOON OF 25OCT2020 WHEN HE STARTED TO EXPERIENCE LIGHTHEADEDNESS AND BLURRY VISION. PATIENT STATES THAT HE SAT DOWN AND WAITED ABOUT 10 MINUTES BEFORE HE DECIDED TO CALL HIS WIFE TO PICK HIM UP FROM WORK TO TAKE HIM TO THE HOSPITAL. WHILE WAITING FOR HIS WIFE TO PICK HIM UP, PATIENT STATES THAT HE WAS TALKING WITH A COWORKER WHO NOTICED THAT HIS LEFT EYE BEGAN TO DRIFT LEFT, WHILE HIS RIGHT EYE REMAINED STATIONARY. UPON ARRIVAL TO THE ER, PATIENT STATES DOCTORS ORDERED A CT SCAN WHICH SHOWED EVIDENCE OF A STROKE. HOWEVER, PATIENT WAS UNABLE TO PROVIDE ANY INFORMATION AS TO WHERE THE STROKE ORIGINATED OR ITS SEVERITY. PATIENT ALSO STATES THAT HE WAS GIVEN AN "ECHOGRAM" BUT HAD NO FURTHER INFORMATION AND WAS UNSURE IF IT WAS ACTUALLY AN ECHOCARDIOGRAM. IN REGARDS TO MEDICATION, PATIENT STATES THAT HE WAS GIVEN AN UNKNOWN BLOOD THINNER, WHICH HE ATTRIBUTES TO FEELING BETTER AND RESTORING HIS VISION. AS OF TODAY, 26OCT2020, PATIENT IS STILL IN ICU AWAITING A FOLLOW-UP MRI AND CT SCAN. NO FURTHER INFORMATION IS AVAILABLE AT THIS TIME. MEDICAL RECORDS WILL BE REQUESTED AS SOON AS POSSIBLE. UPDATE 27OCT2020: Patient states he was moved out of ICU today. Neurologist explained to patient that the stroke seems to have taken place in the right side of the occipital | Antonio Gutierrez (b) (4) | 27 Oct 2020 20:07:52 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

[Narrative](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| <p>lobe, with no further information available at this time. Follow-up MRI and CT scan information not yet available, as patient is to meet with neurologist to discuss. Patient also states that his heart went into atrial fibrillation on Sunday, 25OCT2020, twice, so a cardiology consult has been requested. As of 27OCT2020, patient states that he has been started on blood thinners, but name or type is unknown. Patient remains hospitalized, though now out of ICU.'</p> <p>reason for change: New Information</p> <p>User entered 'Patient contacted staff on 26OCT2020 to state that he had been hospitalized in the ICU due to a stroke that occurred on 25OCT2020. According to the patient, he had been at work on the afternoon of 25OCT2020 when he started to experience lightheadedness and blurry vision. Patient states that he sat down and waited about 10 minutes before he decided to call his wife to pick him up from work to take him to the hospital. While waiting for his wife to pick him up, patient states that he was talking with a coworker who noticed that his left eye began to drift left, while his right eye remained stationary. Upon arrival to the ER, patient states doctors ordered a CT scan which showed evidence of a stroke. However, patient was unable to provide any information as to where the stroke originated or its severity. Patient also states that he was given an "echogram" but had no further information and was unsure if it was actually an echocardiogram. In regards to medication, patient states that he was given an unknown blood thinner, which he attributes to feeling better and restoring his vision. As of today, 26OCT2020, patient is still in ICU awaiting a follow-up MRI and CT scan. No further information is available at this time. Medical records will be requested as soon as possible.'</p> | | |
| | Antonio Gutierrez (b) (4) | 26 Oct 2020 19:35:20 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 26 Oct 2020 19:35:20 |

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 26 Oct 2020 19:35:20 |

US3292312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 26 Oct 2020 19:35:20 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Mar 2021 17:51:06 |
| User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 11 Feb 2021 15:37:59 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 11 Feb 2021 15:37:59 |
| Data point term sent to Coder | System | 11 Feb 2021 15:37:12 |
| User entered 'Constipation' | (b) (4), (b) (6) | 11 Feb 2021 15:36:19 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Mar 2021 17:51:06 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 11 Feb 2021 15:36:19 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:51:06 |
| User entered 'No (N)' | (b) (4), (b) (6) | 11 Feb 2021 15:36:19 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:51:06 |
| User entered 'No (N)' | (b) (4), (b) (6) | 11 Feb 2021 15:36:19 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:51:06 |
| User entered '25 Oct 2020' | | 11 Feb 2021 15:36:19 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:51:06 |
| User entered empty. | | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User entered empty. | System | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:51:06 |
| User entered 'No (N)' | (b) (4), (b) (6) | 11 Feb 2021 15:36:19 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:51:06 |
| User entered '29 Oct 2020' | | 11 Feb 2021 15:36:19 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:51:06 |
| User entered empty. | | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User entered empty. | System | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Severity](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:51:06 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4), (b) (6) | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Mar 2021 17:51:06 |
| User entered 'No (N)' | (b) (4), (b) (6) | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:51:06 |
| User entered '0' | | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:51:06 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:51:06 |
| User entered '0' | | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:51:06 |
| User entered empty. | | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:51:06 |
| User entered empty. | | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:51:06 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 15:36:19 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:51:06 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:51:06 |
| User entered '0' | | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:51:06 |
| User entered '0' | | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:51:06 |
| User entered '0' | | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:51:06 |
| User entered 'Not Related (NOT RELATED)' | | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:51:06 |
| User entered 'Not Related (NOT RELATED)' | | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) |
| User entered 'Not Applicable (NOT APPLICABLE)' | | 23 Mar 2021 17:51:06 |
| | | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:51:06 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:51:06 |
| User entered 'l' | | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:51:06 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Outcome](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:51:06 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:51:06 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:51:06 |
| User entered 'Per hospital medical records' | (b) (4), (b) (6) | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User entered '0' | System | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |
| User entered 'I' | System | 11 Feb 2021 15:36:19 |

US3292312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:22 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Mar 2021 17:51:44 |
| User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0. | Coder Import (b) (4) | 11 Feb 2021 15:41:54 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 11 Feb 2021 15:41:54 |
| Data point term sent to Coder | System | 11 Feb 2021 15:41:19 |
| User entered 'Nausea' | (b) (4), (b) (6) | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:51:44 |
| User entered 'Yes (Y)' | | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Mar 2021 17:51:44 |
| User entered 'No (N)' | (b) (4), (b) (6) | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:51:44 |
| User entered 'No (N)' | (b) (4), (b) (6) | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:51:44 |
| User entered '25 Oct 2020' | | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:51:44 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User entered empty. | System | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:51:44 |
| User entered 'No (N)' | | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:51:44 |
| User entered '29 Oct 2020' | (b) (4), (b) (6) | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:51:44 |
| User entered empty. | | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User entered empty. | System | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Severity](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:51:44 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:51:44 |
| User entered 'No (N)' | | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:51:44 |
| User entered '0' | | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:51:44 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:51:44 |
| User entered '0' | | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:51:44 |
| User entered empty. | | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:51:44 |
| User entered empty. | | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:51:44 |
| User entered empty. | | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:51:44 |
| User entered empty. | | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:51:44 |
| User entered '0' | | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:51:44 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:51:44 |
| User entered '0' | | 11 Feb 2021 15:40:31 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:51:44 |
| User entered 'Not Related (NOT RELATED)' | | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:51:44 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:51:44 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6) | 11 Feb 2021 15:40:31 |

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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:30:59

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:51:44 |
| User entered '0' | | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:51:44 |
| User entered 'l' | (b) (4), (b) (6) | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:51:44 |
| User entered '0' | | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Outcome](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:51:44 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4), (b) (6) | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:51:44 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:51:44 |
| User entered 'per hospital medical records' | | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User entered '0' | System | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |
| User entered 'I' | System | 11 Feb 2021 15:40:31 |

US3292312

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:30 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Mar 2021 17:52:32 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: UTI - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 11 Feb 2021 15:43:54 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 11 Feb 2021 15:43:54 |
| Data point term sent to Coder | System | 11 Feb 2021 15:43:23 |
| User entered 'UTI' | (b) (4), (b) (6) | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:52:32 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:52:32 |
| User entered 'No (N)' | (b) (4), (b) (6) | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:52:32 |
| User entered 'No (N)' | | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:52:32 |
| User entered '26 Oct 2020' | | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:52:32 |
| User entered empty. | | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User entered empty. | System | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:52:32 |
| User entered 'No (N)' | (b) (4), (b) (6) | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Mar 2021 17:52:32 |
| User entered '29 Oct 2020' | | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:52:32 |
| User entered empty. | | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User entered empty. | System | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Severity](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:52:32 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4), (b) (6) | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:52:32 |
| User entered 'No (N)' | | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:52:32 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Mar 2021 17:52:32 |
| User entered '0' | | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:52:32 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:52:32 |
| User entered empty. | | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:52:32 |
| User entered empty. | | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:52:32 |
| User entered empty. | | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:52:32 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:52:32 |
| User entered '0' | | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:52:32 |
| User entered '0' | | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:52:32 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Mar 2021 17:52:32 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:52:32 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:52:32 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6) | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:52:32 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:52:32 |
| User entered 'l' | | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:52:32 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Outcome](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:52:32 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4), (b) (6) | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:52:32 |
| User entered empty. | | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:52:32 |
| User entered 'per hospital medical records' | (b) (4), (b) (6) | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User entered '0' | System | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |
| User entered 'I' | System | 11 Feb 2021 15:42:48 |

US3292312

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:37 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Mar 2021 17:53:13 |
| User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 11 Feb 2021 15:47:57 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 11 Feb 2021 15:47:57 |
| Data point term sent to Coder | System | 11 Feb 2021 15:47:26 |
| User entered 'GERD' | (b) (4), (b) (6) | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:53:13 |
| User entered 'Yes (Y)' | | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:53:13 |
| User entered 'No (N)' | (b) (4), (b) (6) | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:53:13 |
| User entered 'No (N)' | | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:53:13 |
| User entered '25 Oct 2020' | (b) (4), (b) (6) | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:53:13 |
| User entered empty. | | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User entered empty. | System | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:53:13 |
| User entered 'No (N)' | | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:53:13 |
| User entered '29 Oct 2020' | (b) (4), (b) (6) | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:53:13 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User entered empty. | System | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[Severity](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:53:13 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4), (b) (6) | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:53:13 |
| User entered 'No (N)' | (b) (4), (b) (6) | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:53:13 |
| User entered '0' | | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:53:13 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Mar 2021 17:53:13 |
| User entered '0' | | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:53:13 |
| User entered empty. | | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:53:13 |
| User entered empty. | | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:53:13 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:53:13 |
| User entered empty. | | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:53:13 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:53:13 |
| User entered '0' | | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:53:13 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:53:13 |
| User entered 'Not Related (NOT RELATED)' | | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:53:13 |
| User entered 'Not Related (NOT RELATED)' | | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:53:13 |
| User entered 'Not Applicable (NOT APPLICABLE)' | | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:53:13 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:53:13 |
| User entered 'l' | (b) (4), (b) (6) | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:53:13 |
| User entered '0' | | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[Outcome](#)

| Audit | User | Time (GMT) |
|---|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:53:13 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:53:13 |
| User entered empty. | | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:53:13 |
| User entered 'per hospital medical records' | | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User entered '0' | System | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |
| User entered 'I' | System | 11 Feb 2021 15:47:05 |

US3292312

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:53 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Mar 2021 17:54:33 |
| User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Depressed level of consciousness, LLT: Arousal difficult - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 11 Feb 2021 20:01:57 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 11 Feb 2021 20:01:57 |
| Data point term sent to Coder | System | 11 Feb 2021 15:49:28 |
| User entered 'Arousal difficulty' | (b) (4), (b) (6) | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:54:33 |
| User entered 'Yes (Y)' | | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:54:33 |
| User entered 'No (N)' | | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:54:33 |
| User entered 'No (N)' | | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 21:01:57 |
| User closed query 'Per source, Start date is UNK OCT 2020' (Site from CRA). | | 31 Mar 2021 21:01:30 |
| Query 'Per source, Start date is UNK OCT 2020' answered with 'updated source' (Site from CRA). | Dawn Killian (b) (4) (b) (4) | 23 Mar 2021 19:05:26 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 23 Mar 2021 17:54:40 |
| DataPoint Verified. | | 23 Mar 2021 17:54:33 |
| User opened query 'Per source, Start date is UNK OCT 2020' (Site from CRA). | | 23 Mar 2021 17:54:06 |
| User entered '25 Oct 2020' | | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:54:33 |
| User entered empty. | | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User entered empty. | System | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Mar 2021 17:54:33 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 11 Feb 2021 15:52:18 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 11 Feb 2021 15:52:18 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 11 Feb 2021 15:52:18 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 11 Feb 2021 15:49:13 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 31 Mar 2021 21:01:57 |
| User closed query 'Per source, Stop date is UNK OCT 2020' (Site from CRA). | | 31 Mar 2021 21:01:44 |
| Query 'Per source, Stop date is UNK OCT 2020' answered with 'updated source' (Site from CRA). | Dawn Killian (b) (4) | 23 Mar 2021 19:05:31 |
| DataPoint Un-verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:54:37 |
| DataPoint Verified. | | 23 Mar 2021 17:54:33 |
| User opened query 'Per source, Stop date is UNK OCT 2020' (Site from CRA). | | 23 Mar 2021 17:54:15 |
| User entered '29 Oct 2020' | | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:54:33 |
| User entered empty. | | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User entered empty. | System | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[Severity](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:54:33 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4), (b) (6) | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:54:33 |
| User entered 'No (N)' | | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:54:33 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:54:33 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:54:33 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:54:33 |
| User entered empty. | | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:54:33 |
| User entered empty. | | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Mar 2021 17:54:33 |
| User entered empty. | | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:54:33 |
| User entered empty. | | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:54:33 |
| User entered '0' | | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:54:33 |
| User entered '0' | | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:54:33 |
| User entered '0' | | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Mar 2021 17:54:33 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 11 Feb 2021 15:52:53 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 11 Feb 2021 15:52:53 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | (b) (4), (b) (6) | 11 Feb 2021 15:52:53 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 11 Feb 2021 15:49:13 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Mar 2021 17:54:33 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 11 Feb 2021 15:52:53 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 11 Feb 2021 15:52:53 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | (b) (4), (b) (6) | 11 Feb 2021 15:52:53 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 11 Feb 2021 15:49:13 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 15:49:13 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:54:33 |
| User entered 'Not Applicable (NOT APPLICABLE)' | | 11 Feb 2021 15:49:13 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:54:33 |
| User entered '0' | | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:54:33 |
| User entered 'l' | | 11 Feb 2021 15:49:13 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:54:33 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[Outcome](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:54:33 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4), (b) (6) | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:54:33 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:54:33 |
| User entered 'per hospital medical records' | | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User entered '0' | System | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |
| User entered 'I' | System | 11 Feb 2021 15:49:13 |

US3292312

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:58 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Mar 2021 17:55:11 |
| User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 11 Feb 2021 21:36:01 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 11 Feb 2021 21:36:01 |
| Data point term sent to Coder | System | 11 Feb 2021 21:35:23 |
| User entered 'Atrial Fibrillation' | (b) (4), (b) (6) | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:55:11 |
| User entered 'Yes (Y)' | | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:55:11 |
| User entered 'No (N)' | (b) (4), (b) (6) | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:55:11 |
| User entered 'No (N)' | | 11 Feb 2021 21:35:18 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:55:11 |
| User entered '25 Oct 2020' | | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:55:11 |
| User entered empty. | | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User entered empty. | System | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Mar 2021 17:55:11 |
| User entered 'No (N)' reason for change: New Information | Gerardo Pena (b) (4) | 23 Feb 2021 15:24:49 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Mar 2021 17:55:11 |
| User entered '25 Oct 2020' reason for change: New Information | Gerardo Pena (b) (4) | 23 Feb 2021 15:24:49 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 21:35:18 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:55:11 |
| User entered empty. | | 11 Feb 2021 21:35:18 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User entered empty. | System | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[Severity](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:55:11 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:55:11 |
| User entered 'No (N)' | | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:55:11 |
| User entered '0' | | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:55:11 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:55:11 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:55:11 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:55:11 |
| User entered empty. | | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:55:11 |
| User entered empty. | | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:55:11 |
| User entered empty. | | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Mar 2021 17:55:11 |
| User entered '0' | | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:55:11 |
| User entered '0' | | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Mar 2021 17:55:11 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:55:11 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:55:11 |
| User entered 'Not Related (NOT RELATED)' | | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Mar 2021 17:55:11 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6) | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:55:11 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | 23 Mar 2021 17:55:11 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM). | (b) (4), (b) (6) | 24 Mar 2021 11:07:53 |
| Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'updated' (Site from DM). | Dawn Killian (b) (4) | 23 Mar 2021 19:11:33 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Mar 2021 17:55:11 |
| User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM). | (b) (4), (b) (6) | 02 Mar 2021 04:56:59 |
| User entered 'I' | | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[Outcome](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Mar 2021 17:55:11 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information | Gerardo Pena (b) (4) | 23 Feb 2021 15:24:49 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | (b) (4), (b) (6) | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) 23 Mar 2021 17:55:11 |
| User entered empty. | | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 17:55:11 |
| User entered 'per hospital medical records' | | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User entered '0' | System | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |
| User entered 'I' | System | 11 Feb 2021 21:35:18 |

US3292312

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:01 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User coded data point as SOC: Cardiac disorders, HLT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure, LLT: Heart failure, unspecified - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 25 Apr 2021 13:03:42 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 25 Apr 2021 13:03:42 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| Data point term sent to Coder | System | 21 Apr 2021 20:32:26 |
| User entered 'Acute on chronic systolic and diastolic dysfunction' | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered 'No (N)' | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered 'No (N)' | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered '25 Oct 2020' | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered empty. | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User entered empty. | System | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered 'No (N)' | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | System | 21 Apr 2021 20:32:48 |
| Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System). | System | 21 Apr 2021 20:32:48 |
| User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | System | 21 Apr 2021 20:31:52 |
| User entered '25 Oct 2020' | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered empty. | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User entered empty. | System | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[Severity](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered 'No (N)' | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered '0' | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered '0' | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered '0' | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered empty. | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered empty. | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered empty. | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered empty. | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered '0' | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered '0' | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered '0' | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered 'Not Related (NOT RELATED)' | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered 'Not Related (NOT RELATED)' | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered 'None (NONE)' | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered 'l' | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered '0' | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered '0' | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[Outcome](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 21 Apr 2021 20:32:48 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered empty. | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:53:37 |
| User entered empty. | Nathan Cortez (b) (4) | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User entered '0' | System | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |
| User entered 'I' | System | 21 Apr 2021 20:31:52 |

US3292312

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:48:06 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 05:13:31 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 24 Nov 2020 22:21:52 |
| User closed query 'Per ETRTR: Please update ConMeds and ConProcedures once Medical Records are available for SAE "Stroke", thanks.' (Site from CRA). | | 06 Nov 2020 18:52:35 |
| Query 'Per ETRTR: Please update ConMeds and ConProcedures once Medical Records are available for SAE "Stroke", thanks.' answered with 'PER SUBJECT A BLOOD THINNER WAS GIVEN BUT HE IS NOT SURE EXACTLY WHAT IS WAS, SUBJECT WAS STILL IN ICU AS OF 26OCT2020, CRC WILL OBTAIN MED RECS ASAP.' (Site from CRA). | Victoria Hernandez (b) (4) | 06 Nov 2020 17:20:23 |
| | (b) (4) | |
| User opened query 'Per ETRTR: Please update ConMeds and ConProcedures once Medical Records are available for SAE "Stroke", thanks.' (Site from CRA). | (b) (4), (b) (6) | 29 Oct 2020 21:34:12 |
| User entered 'Yes (Y)' | | 27 Aug 2020 16:20:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:30:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 23:21:35 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: BABY ASPIRIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Sep 2020 21:30:45 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Sep 2020 21:30:45 |
| Data point term sent to Coder Coding entries removed. | System | 22 Sep 2020 21:29:18 |
| | Dawn Killian (b) (4) | 22 Sep 2020 21:28:18 |
| | (b) (4) | |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: BABY ASPIRIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 27 Aug 2020 19:34:35 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 27 Aug 2020 19:34:35 |
| Data point term sent to Coder | System | 27 Aug 2020 16:21:01 |
| User entered 'BABY ASPIRIN' | (b) (4), (b) (6) | 27 Aug 2020 16:20:41 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:30:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Apr 2021 21:10:18 |
| User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM). | | 29 Mar 2021 13:50:43 |
| Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM). | Dawn Killian (b) (4) | 26 Mar 2021 23:07:54 |
| DataPoint Un-verified. | (b) (4) | |
| | Dawn Killian (b) (4) | 26 Mar 2021 23:07:45 |
| Signature has been broken. | (b) (4) | |
| | Dawn Killian (b) (4) | 26 Mar 2021 23:07:45 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) | 26 Mar 2021 23:07:45 |
| User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM). | (b) (4), (b) (6) | 26 Mar 2021 09:03:26 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Nov 2020 23:21:35 |
| User entered 'No (N)' | | 27 Aug 2020 16:20:41 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:21:35 |
| User entered 'heart health' reason for change: Data Entry Error | Dawn Killian (b) (4) | 22 Sep 2020 21:28:18 |
| User entered 'HYPERTENSION' | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 16:20:41 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered '81' | (b) (4), (b) (6) | 27 Aug 2020 16:20:41 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:30:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 27 Aug 2020 16:20:41 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:30:59

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:20:41 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:30:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Nov 2020 23:21:35 |
| User entered 'once daily (QD)' | | 27 Aug 2020 16:20:41 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:30:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:20:41 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:30:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 27 Aug 2020 16:20:41 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:30:59

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:20:41 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:30:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM). DataPoint Verified. | (b) (4), (b) (6) | 07 Dec 2020 10:45:22 |
| | (b) (4), (b) (6) | 04 Nov 2020 23:21:35 |
| Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'updated' (Site from DM). | Dawn Killian (b) (4) | 22 Sep 2020 21:28:10 |
| User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM). | (b) (4), (b) (6) | 22 Sep 2020 11:12:52 |
| User entered 'UN UNK 2010' | | 27 Aug 2020 16:20:41 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 16:20:41 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:21:35 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 16:20:41 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:20:41 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:30:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 16:20:41 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:30:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 27 Aug 2020 16:20:41 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 27 Aug 2020 16:20:41 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 27 Aug 2020 16:20:41 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:21:35 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 27 Aug 2020 19:35:24 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 27 Aug 2020 19:35:24 |
| Data point term sent to Coder | System | 27 Aug 2020 16:22:02 |
| User entered 'ATORVASTATIN' | (b) (4), (b) (6) | 27 Aug 2020 16:21:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 16:21:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'HYPERCHOLESTEROLEMIA' | (b) (4), (b) (6) | 27 Aug 2020 16:21:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered '80' | (b) (4), (b) (6) | 27 Aug 2020 16:21:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 27 Aug 2020 16:21:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:21:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 27 Aug 2020 16:21:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:59

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:21:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Nov 2020 23:21:35 |
| User entered 'Oral (ORAL)' | | 27 Aug 2020 16:21:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:59

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:21:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'UN UNK 2010' | (b) (4), (b) (6) | 27 Aug 2020 16:21:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 16:21:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:21:35 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 16:21:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:21:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 16:21:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 27 Aug 2020 16:21:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 27 Aug 2020 16:21:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 27 Aug 2020 16:21:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:30:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:21:35 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 00:51:43 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 00:51:43 |
| Data point term sent to Coder | System | 27 Aug 2020 16:22:04 |
| User entered 'CERVEDILOL' | (b) (4), (b) (6) | 27 Aug 2020 16:21:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:30:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 16:21:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'HYPERTENSION' | (b) (4), (b) (6) | 27 Aug 2020 16:21:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered '12.5' | (b) (4), (b) (6) | 27 Aug 2020 16:21:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:30:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 27 Aug 2020 16:21:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:30:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:21:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:30:59

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'twice daily (BID)' | (b) (4), (b) (6) | 27 Aug 2020 16:21:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:30:59

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:21:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:30:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 27 Aug 2020 16:21:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:30:59

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:21:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered '28 Feb 2019' | (b) (4), (b) (6) | 27 Aug 2020 16:21:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 16:21:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 16:21:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:21:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:30:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 16:21:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:30:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 27 Aug 2020 16:21:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 27 Aug 2020 16:21:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 27 Aug 2020 16:21:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---|--|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:21:35 |
| 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) | 23 Sep 2020 12:12:54 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 23 Sep 2020 12:12:54 |
| Data point term sent to Coder Coding entries removed. | System Dawn Killian (b) (4) (b) (4) | 22 Sep 2020 21:30:18 22 Sep 2020 21:29:43 |
| 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) | 28 Aug 2020 11:01:46 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 11:01:46 |
| Data point term sent to Coder User entered 'LISINOPRIL' | System (b) (4), (b) (6) | 27 Aug 2020 16:23:05 27 Aug 2020 16:22:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 16:22:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 23:21:35 |
| User closed query 'Per DM CLR: Please update the indication to reflect the location/type of EDEMA. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM). | | 07 Oct 2020 12:56:30 |
| Query 'Per DM CLR: Please update the indication to reflect the location/type of EDEMA. Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'updated' (Site from DM). | Dawn Killian (b) (4) | 22 Sep 2020 21:29:47 |
| User entered 'HYPERTENSION/cardiac EDEMA' reason for change: Data Entry Error | (b) (4) | 22 Sep 2020 21:29:43 |
| User opened query 'Per DM CLR: Please update the indication to reflect the location/type of EDEMA. Please reconcile with the AE and Med History eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 22 Sep 2020 12:27:01 |
| User entered 'HYPERTENSION/EDEMA' | | 27 Aug 2020 16:22:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered '5' | (b) (4), (b) (6) | 27 Aug 2020 16:22:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 27 Aug 2020 16:22:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:22:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 27 Aug 2020 16:22:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:59

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:22:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 27 Aug 2020 16:22:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:22:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'UN Mar 2019' | (b) (4), (b) (6) | 27 Aug 2020 16:22:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 16:22:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 16:22:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:22:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 16:22:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 27 Aug 2020 16:22:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 27 Aug 2020 16:22:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 27 Aug 2020 16:22:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:30:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:21:35 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: EPLERENONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 27 Aug 2020 19:35:42 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 27 Aug 2020 19:35:42 |
| Data point term sent to Coder | System | 27 Aug 2020 16:24:11 |
| User entered 'eplerenone' | (b) (4), (b) (6) | 27 Aug 2020 16:23:07 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:30:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 16:23:07 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'HYPERTENSION' | (b) (4), (b) (6) | 27 Aug 2020 16:23:07 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered '12.5' | (b) (4), (b) (6) | 27 Aug 2020 16:23:07 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:30:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 27 Aug 2020 16:23:07 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:30:59

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:23:07 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:30:59

[Frequency](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'other (OTHER)' | (b) (4), (b) (6) | 27 Aug 2020 16:23:07 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:30:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered '3X A WEEK' | (b) (4), (b) (6) | 27 Aug 2020 16:23:07 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:30:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 27 Aug 2020 16:23:07 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:30:59

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Nov 2020 23:21:35 |
| User entered empty. | | 27 Aug 2020 16:23:07 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered '30 Jun 2020' | (b) (4), (b) (6) | 27 Aug 2020 16:23:07 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 16:23:07 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 16:23:07 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:23:07 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:30:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 16:23:07 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:30:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Aug 2020 16:23:07 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Aug 2020 16:23:07 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Aug 2020 16:23:07 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:30:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---|--|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:21:35 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 23 Sep 2020 18:38:39 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 23 Sep 2020 18:38:39 |
| Data point term sent to Coder Coding entries removed. | System Dawn Killian (b) (4) (b) (4) | 23 Sep 2020 18:37:22 23 Sep 2020 18:37:17 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 27 Aug 2020 19:35:43 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 27 Aug 2020 19:35:43 |
| Data point term sent to Coder User entered 'plavix' | System (b) (4), (b) (6) | 27 Aug 2020 16:24:11 27 Aug 2020 16:23:46 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:30:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 16:23:46 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 06 Nov 2020 18:56:00 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 04 Nov 2020 23:21:58 |
| DataPoint Verified. | | 04 Nov 2020 23:21:35 |
| User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM). | | 07 Oct 2020 12:57:01 |
| Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'updated' (Site from DM). | Dawn Killian (b) (4) | 23 Sep 2020 18:37:32 |
| User entered 'CAD' reason for change: Data Entry Error | (b) (4) | 23 Sep 2020 18:37:17 |
| User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 23 Sep 2020 04:11:57 |
| User entered 'edema' | | 27 Aug 2020 16:23:46 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered '75' | (b) (4), (b) (6) | 27 Aug 2020 16:23:46 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:30:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 27 Aug 2020 16:23:46 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:30:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:23:46 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:30:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'every other day (QOD)' | (b) (4), (b) (6) | 27 Aug 2020 16:23:46 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:30:59

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:23:46 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:30:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:21:35 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 27 Aug 2020 16:23:46 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:30:59

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:23:46 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:30:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|--|--|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User closed query 'Per CDM: Response noted ' CAD started 2009' however corresponding Medical Hist record (#11) CARDIAC EDEMA (CAD) is recorded with a start date of 'FEB-2019'? Please review and update MH record as per your response and reconcile dates/indication name. Thanks.' (Site from DM). Query 'Per CDM: Response noted ' CAD started 2009' however corresponding Medical Hist record (#11) CARDIAC EDEMA (CAD) is recorded with a start date of 'FEB-2019'? Please review and update MH record as per your response and reconcile dates/indication name. Thanks.' answered with 'CAD = coronary artery disease. Start date = 2009' (Site from DM). | (b) (4), (b) (6) Gerardo Pena (b) (4) | 31 Dec 2020 03:41:27 29 Dec 2020 22:56:23 |
| User opened query 'Per CDM: Response noted ' CAD started 2009' however corresponding Medical Hist record (#11) CARDIAC EDEMA (CAD) is recorded with a start date of 'FEB-2019'? Please review and update MH record as per your response and reconcile dates/indication name. Thanks.' (Site from DM). | (b) (4), (b) (6) | 11 Nov 2020 12:18:36 |
| User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM). DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 11 Nov 2020 12:14:31 |
| Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'CAD started 2009' (Site from DM). | (b) (4), (b) (6) Dawn Killian (b) (4) | 04 Nov 2020 23:21:35 23 Sep 2020 18:37:51 |
| User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM). User entered 'un UNK 2010' | (b) (4), (b) (6) | 23 Sep 2020 04:12:06 27 Aug 2020 16:23:46 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 16:23:46 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 16:23:46 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Nov 2020 23:21:35 |
| User entered empty. | | 27 Aug 2020 16:23:46 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:30:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 16:23:46 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:30:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 27 Aug 2020 16:23:46 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 27 Aug 2020 16:23:46 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 27 Aug 2020 16:23:46 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:30:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:21:35 |
| 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) | 27 Aug 2020 19:35:51 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 27 Aug 2020 19:35:51 |
| Data point term sent to Coder | System | 27 Aug 2020 16:25:17 |
| User entered 'synjardy' | (b) (4), (b) (6) | 27 Aug 2020 16:24:44 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:30:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 16:24:44 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'type 2 diabetes' | (b) (4), (b) (6) | 27 Aug 2020 16:24:44 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 21 Apr 2021 20:47:34 |
| User closed query 'Source has thi sdrug listed twice, once on the MH pages 2of5 with a dose of 12.5 mg x2 QD and on the yellow con med page 2of_ as 25 mg (which is 12.5 x2) but there is no mention of 5/500 dosing. please review and confirm.' (Site from CRA). | | 21 Apr 2021 20:44:57 |
| Query 'Source has thi sdrug listed twice, once on the MH pages 2of5 with a dose of 12.5 mg x2 QD and on the yellow con med page 2of_ as 25 mg (which is 12.5 x2) but there is no mention of 5/500 dosing. please review and confirm.' answered with 'Reconciled' (Site from CRA). | Nathan Cortez (b) (4) | 21 Apr 2021 20:36:31 |
| Signature has been broken. | Nathan Cortez (b) (4) | 21 Apr 2021 20:36:24 |
| User entered '25' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 21 Apr 2021 20:36:24 |
| User opened query 'Source has thi sdrug listed twice, once on the MH pages 2of5 with a dose of 12.5 mg x2 QD and on the yellow con med page 2of_ as 25 mg (which is 12.5 x2) but there is no mention of 5/500 dosing. please review and confirm.' (Site from CRA). | (b) (4), (b) (6) | 16 Apr 2021 18:22:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| 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 40/1680).' (Site from DM). | (b) (4), (b) (6) | 30 Nov 2020 12:41:38 |
| 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 40/1680).' answered with 'UPDATED' (Site from DM). | Victoria Hernandez (b) (4) | 05 Nov 2020 23:27:09 |
| DataPoint Un-verified. | Victoria Hernandez (b) (4) | 05 Nov 2020 23:27:01 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| User entered '5/500' reason for change: Data Entry Error | Victoria Hernandez (b) (4) | 05 Nov 2020 23:27:01 |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Nov 2020 23:21:35 |
| 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 40/1680).' (Site from DM). | (b) (4) | 21 Oct 2020 02:27:52 |
| 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., 12.5/500).' (Site from DM). | (b) (4) | 07 Oct 2020 12:57:55 |
| 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., 12.5/500).' answered with 'updated' (Site from DM). | Dawn Killian (b) (4) | 23 Sep 2020 18:38:48 |
| User entered '25' reason for change: Data Entry Error | Dawn Killian (b) (4) | 23 Sep 2020 18:38:39 |
| 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., 12.5/500).' (Site from DM). | (b) (4), (b) (6) | 23 Sep 2020 04:16:51 |
| User entered '12.5 x 2' | (b) (4) | 27 Aug 2020 16:24:44 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:30:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 27 Aug 2020 16:24:44 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:30:59

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:24:44 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:30:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 27 Aug 2020 16:24:44 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:30:59

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:24:44 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:30:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 27 Aug 2020 16:24:44 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:30:59

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:24:44 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:30:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'un Jun 2019' | (b) (4), (b) (6) | 27 Aug 2020 16:24:44 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 16:24:44 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 16:24:44 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:24:44 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:30:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 16:24:44 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:30:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 27 Aug 2020 16:24:44 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 27 Aug 2020 16:24:44 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 27 Aug 2020 16:24:44 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:30:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:21:35 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EICOSAPENTAENOIC ACID ETHYL ESTER, PRODUCTSYNONYM: VASCEPA - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 16 Sep 2020 07:27:33 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 16 Sep 2020 07:27:33 |
| Data point term sent to Coder | System | 27 Aug 2020 16:27:21 |
| User entered 'vascepa/icosapent' | (b) (4), (b) (6) | 27 Aug 2020 16:26:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:30:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 16:26:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'hypertriglyceridemia' | (b) (4), (b) (6) | 27 Aug 2020 16:26:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered '2' | (b) (4), (b) (6) | 27 Aug 2020 16:26:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:30:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'g (g)' | (b) (4), (b) (6) | 27 Aug 2020 16:26:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:30:59

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:26:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:30:59

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'twice daily (BID)' | (b) (4), (b) (6) | 27 Aug 2020 16:26:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:30:59

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:26:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:30:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 27 Aug 2020 16:26:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:30:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:26:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered '28 Feb 2019' | (b) (4), (b) (6) | 27 Aug 2020 16:26:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 16:26:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 16:26:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:26:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:30:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 16:26:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:30:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 27 Aug 2020 16:26:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 27 Aug 2020 16:26:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 27 Aug 2020 16:26:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:30:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---|--|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:21:35 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: BUMETANIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 22 Sep 2020 22:12:42 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 22 Sep 2020 22:12:42 |
| Data point term sent to Coder Coding entries removed. | System Dawn Killian (b) (4) (b) (4) | 22 Sep 2020 21:31:19 22 Sep 2020 21:30:23 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: BUMETANIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 27 Aug 2020 22:13:57 |
| 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 Aug 2020 22:13:57 |
| Data point term sent to Coder User entered 'bumetanide' | System (b) (4), (b) (6) | 27 Aug 2020 16:28:24 27 Aug 2020 16:27:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:30:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'No (N)' | (b) (4), (b) (6) | 7 Aug 2020 16:27:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 24 Nov 2020 22:23:05 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 04 Nov 2020 23:21:39 |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Nov 2020 23:21:35 |
| User closed query 'Per DM CLR: Please update the indication to reflect the location/type of EDEMA. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 07 Oct 2020 12:58:16 |
| Query 'Per DM CLR: Please update the indication to reflect the location/type of EDEMA. Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'updated' (Site from DM). | Dawn Killian (b) (4) | 22 Sep 2020 21:30:28 |
| User entered 'cardiac EDEMA' reason for change: | Dawn Killian (b) (4) | 22 Sep 2020 21:30:23 |
| Data Entry Error | (b) (4) | |
| User opened query 'Per DM CLR: Please update the indication to reflect the location/type of EDEMA. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 22 Sep 2020 11:17:30 |
| User entered 'edema' | (b) (4), (b) (6) | 27 Aug 2020 16:27:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). DataPoint Verified. | (b) (4), (b) (6) | 28 Nov 2020 18:03:39 |
| | (b) (4), (b) (6) | 04 Nov 2020 23:21:35 |
| Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'correct per patient' (Site from DM). | Dawn Killian (b) (4) | 22 Sep 2020 21:30:41 |
| User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). | (b) (4), (b) (6) | 22 Sep 2020 11:17:39 |
| User entered '0.05' | | 27 Aug 2020 16:27:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:30:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 27 Aug 2020 16:27:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:30:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:27:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:30:59

[Frequency](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'other (OTHER)' | (b) (4), (b) (6) | 27 Aug 2020 16:27:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:30:59

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered '4x week' | (b) (4), (b) (6) | 27 Aug 2020 16:27:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:30:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 27 Aug 2020 16:27:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:30:59

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:27:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:30:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'un Mar 2019' | (b) (4), (b) (6) | 27 Aug 2020 16:27:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 16:27:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 16:27:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 16:27:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:30:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:21:35 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 16:27:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:30:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Aug 2020 16:27:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Aug 2020 16:27:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Aug 2020 16:27:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:23:20 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 14 Apr 2021 06:56:51 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 14 Apr 2021 06:56:51 |
| Data point term sent to Coder | System | 13 Apr 2021 19:41:37 |
| Coding entries removed. | Dawn Killian (b) (4) | 13 Apr 2021 19:41:04 |
| User signature succeeded. | (b) (4) | |
| | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Feb 2021 22:40:57 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Feb 2021 22:40:57 |
| Data point term sent to Coder | System | 11 Feb 2021 14:24:06 |
| User entered 'apixaban' | (b) (4), (b) (6) | 11 Feb 2021 14:23:15 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:23:20 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 11 Feb 2021 14:23:15 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 16 Apr 2021 18:23:20 |
| User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate. | | 16 Apr 2021 09:35:40 |
| ' (Site from DM). | | |
| Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate. | Dawn Killian (b) (4) | 13 Apr 2021 19:41:09 |
| ' answered with 'updated' (Site from DM). | (b) (4) | |
| Signature has been broken. | Dawn Killian (b) (4) | 13 Apr 2021 19:41:04 |
| | (b) (4) | |
| User entered 'PROPHYLAXIS for stroke' reason for change: Data Entry Error | Dawn Killian (b) (4) | 13 Apr 2021 19:41:04 |
| | (b) (4) | |
| User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate. | (b) (4), (b) (6) | 07 Apr 2021 05:12:07 |
| | | |
| ' (Site from DM). | | |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| | (b) (4) | |
| User entered 'prophylaxis' | (b) (4), (b) (6) | 11 Feb 2021 14:23:15 |
| | | |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:23:20 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '5' | (b) (4), (b) (6) | 11 Feb 2021 14:23:15 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:23:20 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 11 Feb 2021 14:23:15 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:59

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:23:20 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 14:23:15 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:59

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:23:20 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'twice daily (BID)' | (b) (4), (b) (6) | 11 Feb 2021 14:23:15 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:23:20 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 14:23:15 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:23:20 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 11 Feb 2021 14:23:15 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:59

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:23:20 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 14:23:15 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:23:20 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '30 Oct 2020' | (b) (4), (b) (6) | 11 Feb 2021 14:23:15 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:23:20 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 14:23:15 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:23:20 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 11 Feb 2021 14:23:15 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:23:20 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 14:23:15 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:23:20 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 11 Feb 2021 14:23:15 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 11 Feb 2021 14:23:15 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 11 Feb 2021 14:23:15 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Feb 2021 14:23:15 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|--|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:34:09 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 14 Apr 2021 08:45:40 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 14 Apr 2021 08:45:40 |
| Data point term sent to Coder Coding entries removed. | System Dawn Killian (b) (4) | 13 Apr 2021 19:41:37 13 Apr 2021 19:41:28 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 04 Mar 2021 23:25:41 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 04 Mar 2021 23:25:41 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| Data point term sent to Coder User entered 'ticagrelor' | System (b) (4), (b) (6) | 11 Feb 2021 14:25:06 11 Feb 2021 14:24:32 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:34:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 11 Feb 2021 14:24:32 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 16 Apr 2021 18:34:09 |
| User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate. | | 16 Apr 2021 09:35:44 |
| ' (Site from DM). | | |
| Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate. | Dawn Killian (b) (4) | 13 Apr 2021 19:41:35 |
| ' answered with 'updated' (Site from DM). | (b) (4) | |
| Signature has been broken. | Dawn Killian (b) (4) | 13 Apr 2021 19:41:28 |
| | (b) (4) | |
| User entered 'PROPHYLAXIS FOR STROKE' | Dawn Killian (b) (4) | 13 Apr 2021 19:41:28 |
| reason for change: Data Entry Error | (b) (4) | |
| User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate. | (b) (4), (b) (6) | 07 Apr 2021 05:12:40 |
| ' (Site from DM). | | |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| | (b) (4) | |
| User entered 'prophylaxis' | (b) (4), (b) (6) | 11 Feb 2021 14:24:32 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:34:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '90' | (b) (4), (b) (6) | 11 Feb 2021 14:24:32 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:34:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 11 Feb 2021 14:24:32 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:59

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:34:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 14:24:32 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:59

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:34:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'twice daily (BID)' | (b) (4), (b) (6) | 11 Feb 2021 14:24:32 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:34:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 14:24:32 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:34:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 11 Feb 2021 14:24:32 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:59

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:34:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 14:24:32 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:34:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '30 Oct 2020' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:24:32 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:34:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 14:24:32 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:34:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 11 Feb 2021 14:24:32 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:34:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 14:24:32 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:34:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 11 Feb 2021 14:24:32 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 11 Feb 2021 14:24:32 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 11 Feb 2021 14:24:32 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Feb 2021 14:24:32 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:21 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:34:04 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 11 Feb 2021 14:28:00 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Feb 2021 14:28:00 |
| Data point term sent to Coder | System | 11 Feb 2021 14:27:13 |
| User entered 'famotidine' | (b) (4), (b) (6) | 11 Feb 2021 14:27:12 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:21 |
| DataPoint Verified. | | 16 Apr 2021 18:34:04 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:27:12 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:21 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:34:04 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'GERD' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:27:12 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:21 |
| DataPoint Verified. | | 16 Apr 2021 18:34:04 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '20' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:27:12 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:21 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:34:04 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 11 Feb 2021 14:27:12 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:59

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:21 |
| DataPoint Verified. | | 16 Apr 2021 18:34:04 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:27:12 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:59

[Frequency](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:21 |
| DataPoint Verified. | | 16 Apr 2021 18:34:04 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'other (OTHER)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:27:12 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:21 |
| DataPoint Verified. | | 16 Apr 2021 18:34:04 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'q12h' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:27:12 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:21 |
| DataPoint Verified. | | 16 Apr 2021 18:34:04 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Intravenous (INTRAVENOUS)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:27:12 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:59

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:21 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:34:04 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 14:27:12 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:21 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:34:04 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '25 Oct 2020' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:27:12 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:21 |
| DataPoint Verified. | | 16 Apr 2021 18:34:04 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:27:12 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:21 |
| DataPoint Verified. | | 16 Apr 2021 18:34:04 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:27:12 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:21 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:34:04 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '29 Oct 2020' | (b) (4), (b) (6) | 11 Feb 2021 14:27:12 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:21 |
| DataPoint Verified. | | 16 Apr 2021 18:34:04 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:27:12 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:21 |
| User entered empty. | System | 11 Feb 2021 14:27:12 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:21 |
| User entered empty. | System | 11 Feb 2021 14:27:12 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:21 |
| User entered empty. | System | 11 Feb 2021 14:27:12 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:26 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MAGNESIUM HYDROXIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Feb 2021 14:44:52 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Feb 2021 14:44:52 |
| Data point term sent to Coder | System | 11 Feb 2021 14:29:14 |
| User entered 'magnesium hydroxide' | (b) (4), (b) (6) | 11 Feb 2021 14:28:21 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:26 |
| DataPoint Verified. | | 16 Apr 2021 18:33:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:28:21 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:26 |
| DataPoint Verified. | | 16 Apr 2021 18:33:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'constipation' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:28:21 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:26 |
| DataPoint Verified. | | 16 Apr 2021 18:33:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '30' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:28:21 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:26 |
| DataPoint Verified. | | 16 Apr 2021 18:33:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'mL (mL)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:28:21 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:59

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:26 |
| DataPoint Verified. | | 16 Apr 2021 18:33:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:28:21 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:26 |
| DataPoint Verified. | | 16 Apr 2021 18:33:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'as needed (PRN)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:28:21 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:26 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 14:28:21 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:26 |
| DataPoint Verified. | | 16 Apr 2021 18:33:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:28:21 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:59

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:26 |
| DataPoint Verified. | | 16 Apr 2021 18:33:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:28:21 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:26 |
| DataPoint Verified. | | 16 Apr 2021 18:33:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '25 Oct 2020' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:28:21 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:26 |
| DataPoint Verified. | | 16 Apr 2021 18:33:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:28:21 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:26 |
| DataPoint Verified. | | 16 Apr 2021 18:33:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:28:21 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:26 |
| DataPoint Verified. | | 16 Apr 2021 18:33:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '29 Oct 2020' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:28:21 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:26 |
| DataPoint Verified. | | 16 Apr 2021 18:33:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:28:21 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:26 |
| User entered empty. | System | 11 Feb 2021 14:28:21 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:26 |
| User entered empty. | System | 11 Feb 2021 14:28:21 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:26 |
| User entered empty. | System | 11 Feb 2021 14:28:21 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:30:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:30 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:54 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 11 Feb 2021 14:30:52 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Feb 2021 14:30:52 |
| Data point term sent to Coder | System | 11 Feb 2021 14:30:15 |
| User entered 'bisacodyl' | (b) (4), (b) (6) | 11 Feb 2021 14:29:37 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:30:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:33:54 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:29:37 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:30 |
| DataPoint Verified. | | 16 Apr 2021 18:33:54 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'constipation' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:29:37 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:30 |
| DataPoint Verified. | | 16 Apr 2021 18:33:54 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '10' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:29:37 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:30:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:30 |
| DataPoint Verified. | | 16 Apr 2021 18:33:54 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:29:37 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:30:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:30 |
| DataPoint Verified. | | 16 Apr 2021 18:33:54 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:29:37 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:30:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:30 |
| DataPoint Verified. | | 16 Apr 2021 18:33:54 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'as needed (PRN)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:29:37 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:30:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:30 |
| DataPoint Verified. | | 16 Apr 2021 18:33:54 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:29:37 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:30:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:30 |
| DataPoint Verified. | | 16 Apr 2021 18:33:54 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Rectal (RECTAL)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:29:37 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:30:59

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:30 |
| DataPoint Verified. | | 16 Apr 2021 18:33:54 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:29:37 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:33:54 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '25 Oct 2020' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:29:37 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:30 |
| DataPoint Verified. | | 16 Apr 2021 18:33:54 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:29:37 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:30 |
| DataPoint Verified. | | 16 Apr 2021 18:33:54 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:29:37 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:30 |
| DataPoint Verified. | | 16 Apr 2021 18:33:54 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '29 Oct 2020' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:29:37 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:30:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:30 |
| DataPoint Verified. | | 16 Apr 2021 18:33:54 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 14:29:37 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:30:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:30 |
| User entered empty. | System | 11 Feb 2021 14:29:37 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:30 |
| User entered empty. | System | 11 Feb 2021 14:29:37 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:30 |
| User entered empty. | System | 11 Feb 2021 14:29:37 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:30:59

Name of Medication

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:34 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:50 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 11 Feb 2021 15:03:54 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Feb 2021 15:03:54 |
| Data point term sent to Coder | System | 11 Feb 2021 15:02:38 |
| User entered 'ondansetron' | (b) (4), (b) (6) | 11 Feb 2021 15:02:05 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:30:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:34 |
| DataPoint Verified. | | 16 Apr 2021 18:33:50 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 11 Feb 2021 15:02:05 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:34 |
| DataPoint Verified. | | 16 Apr 2021 18:33:50 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'nausea' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:02:05 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:33:50 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '4' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:02:05 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:30:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:33:50 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:02:05 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:30:59

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:34 |
| DataPoint Verified. | | 16 Apr 2021 18:33:50 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:02:05 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:30:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:34 |
| DataPoint Verified. | | 16 Apr 2021 18:33:50 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'as needed (PRN)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:02:05 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:30:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:34 |
| DataPoint Verified. | | 16 Apr 2021 18:33:50 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 15:02:05 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:30:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:34 |
| DataPoint Verified. | | 16 Apr 2021 18:33:50 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Intravenous (INTRAVENOUS)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:02:05 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:30:59

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:34 |
| DataPoint Verified. | | 16 Apr 2021 18:33:50 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:02:05 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:34 |
| DataPoint Verified. | | 16 Apr 2021 18:33:50 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '25 Oct 2020' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:02:05 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:34 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:50 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 15:02:05 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:34 |
| DataPoint Verified. | | 16 Apr 2021 18:33:50 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:02:05 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:34 |
| DataPoint Verified. | | 16 Apr 2021 18:33:50 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '29 Oct 2020' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:02:05 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:30:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:34 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:50 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 11 Feb 2021 15:02:05 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:30:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:34 |
| User entered empty. | System | 11 Feb 2021 15:02:05 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:34 |
| User entered empty. | System | 11 Feb 2021 15:02:05 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:34 |
| User entered empty. | System | 11 Feb 2021 15:02:05 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:30:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:38 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:48 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN OPIOID DEPENDENCE, PRODUCT: NALOXONE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 15 Feb 2021 21:41:43 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 15 Feb 2021 21:41:43 |
| Data point term sent to Coder | System | 11 Feb 2021 15:08:43 |
| User entered 'Naloxone' | (b) (4), (b) (6) | 11 Feb 2021 15:07:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:30:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:38 |
| DataPoint Verified. | | 16 Apr 2021 18:33:48 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:07:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:38 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:33:48 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'arousal difficulty' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:07:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:38 |
| DataPoint Verified. | | 16 Apr 2021 18:33:48 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'unknown' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:07:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:30:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:38 |
| DataPoint Verified. | | 16 Apr 2021 18:33:48 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Other (OTHER)' | (b) (4), (b) (6) | 11 Feb 2021 15:07:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:30:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:38 |
| DataPoint Verified. | | 16 Apr 2021 18:33:48 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Unknown' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:07:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:30:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:38 |
| DataPoint Verified. | | 16 Apr 2021 18:33:48 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'as needed (PRN)' | (b) (4), (b) (6) | 11 Feb 2021 15:07:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:30:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:38 |
| DataPoint Verified. | | 16 Apr 2021 18:33:48 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:07:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:30:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:38 |
| DataPoint Verified. | | 16 Apr 2021 18:33:48 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Intravenous (INTRAVENOUS)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:07:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:30:59

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:38 |
| DataPoint Verified. | | 16 Apr 2021 18:33:48 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:07:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:38 |
| DataPoint Verified. | | 16 Apr 2021 18:33:48 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '25 Oct 2020' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:07:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:38 |
| DataPoint Verified. | | 16 Apr 2021 18:33:48 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:07:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:38 |
| DataPoint Verified. | | 16 Apr 2021 18:33:48 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:07:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:38 |
| DataPoint Verified. | | 16 Apr 2021 18:33:48 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '29 Oct 2020' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:07:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:30:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:38 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:48 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 11 Feb 2021 15:07:57 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 11 Feb 2021 15:07:57 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 11 Feb 2021 15:07:57 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 11 Feb 2021 15:07:51 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 15:07:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:30:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:38 |
| User entered empty. | System | 11 Feb 2021 15:07:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:38 |
| User entered empty. | System | 11 Feb 2021 15:07:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:38 |
| User entered empty. | System | 11 Feb 2021 15:07:51 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:30:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:43 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:44 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| 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 - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 13 Feb 2021 00:25:54 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 13 Feb 2021 00:25:54 |
| Data point term sent to Coder | System | 11 Feb 2021 15:12:46 |
| User entered 'ceftriaxone' | (b) (4), (b) (6) | 11 Feb 2021 15:12:36 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:30:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:43 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:33:44 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 11 Feb 2021 15:12:36 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:43 |
| DataPoint Verified. | | 16 Apr 2021 18:33:44 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'UTI' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:12:36 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:43 |
| DataPoint Verified. | | 16 Apr 2021 18:33:44 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'l' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:12:36 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:30:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:43 |
| DataPoint Verified. | | 16 Apr 2021 18:33:44 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'g (g)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:12:36 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:30:59

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:43 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:44 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 15:12:36 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:30:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:43 |
| DataPoint Verified. | | 16 Apr 2021 18:33:44 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 11 Feb 2021 15:12:36 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:30:59

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:43 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:44 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 15:12:36 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:30:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:43 |
| DataPoint Verified. | | 16 Apr 2021 18:33:44 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Intravenous (INTRAVENOUS)' | (b) (4), (b) (6) | 11 Feb 2021 15:12:36 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:30:59

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:43 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:33:44 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:12:36 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:43 |
| DataPoint Verified. | | 16 Apr 2021 18:33:44 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '26 Oct 2020' | (b) (4), (b) (6) | 11 Feb 2021 15:12:36 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:43 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:44 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 15:12:36 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:43 |
| DataPoint Verified. | | 16 Apr 2021 18:33:44 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 11 Feb 2021 15:12:36 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:43 |
| DataPoint Verified. | | 16 Apr 2021 18:33:44 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '29 Oct 2020' | (b) (4), (b) (6) | 11 Feb 2021 15:12:36 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:30:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:43 |
| DataPoint Verified. | | 16 Apr 2021 18:33:44 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 11 Feb 2021 15:12:36 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:30:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:43 |
| User entered 'I' | System | 11 Feb 2021 15:12:36 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:43 |
| User entered 'I' | System | 11 Feb 2021 15:12:36 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:43 |
| User entered '804 (804)' | System | 11 Feb 2021 15:12:36 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:30:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:47 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:40 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 28 Feb 2021 17:19:32 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 28 Feb 2021 17:19:32 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Feb 2021 14:10:39 |
| Data point term sent to Coder | System | 11 Feb 2021 15:15:50 |
| User entered 'Vancomycin' | (b) (4), (b) (6) | 11 Feb 2021 15:14:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:30:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:47 |
| DataPoint Verified. | | 16 Apr 2021 18:33:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:14:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:33:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Prophylaxis of infection' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:14:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:47 |
| DataPoint Verified. | | 16 Apr 2021 18:33:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '250' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:14:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:30:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:47 |
| DataPoint Verified. | | 16 Apr 2021 18:33:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'mL (mL)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:14:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:30:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:47 |
| DataPoint Verified. | | 16 Apr 2021 18:33:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:14:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:30:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:47 |
| DataPoint Verified. | | 16 Apr 2021 18:33:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'three times daily (TID)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:14:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:30:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:47 |
| DataPoint Verified. | | 16 Apr 2021 18:33:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:14:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:30:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:47 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Intravenous (INTRAVENOUS)' | (b) (4), (b) (6) | 11 Feb 2021 15:14:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:30:59

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:33:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:14:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:33:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '26 Oct 2020' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:14:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:47 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 15:14:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:47 |
| DataPoint Verified. | | 16 Apr 2021 18:33:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:14:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:47 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '29 Oct 2020' | (b) (4), (b) (6) | 11 Feb 2021 15:14:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:30:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:47 |
| DataPoint Verified. | | 16 Apr 2021 18:33:40 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:14:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:30:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:47 |
| User entered '3' | System | 11 Feb 2021 15:14:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:47 |
| User entered 'I' | System | 11 Feb 2021 15:14:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:47 |
| User entered '804 (804)' | System | 11 Feb 2021 15:14:52 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:30:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:33:37 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: ENZYMES, PRODUCT: ALTEPLASE, PRODUCTSYNONYM: TPA - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 24 Mar 2021 08:57:31 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 24 Mar 2021 08:57:31 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Feb 2021 14:10:39 |
| Data point term sent to Coder | System | 11 Feb 2021 15:16:51 |
| User entered 'TPA' | (b) (4), (b) (6) | 11 Feb 2021 15:16:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:30:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:00 |
| DataPoint Verified. | | 16 Apr 2021 18:33:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:16:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:00 |
| DataPoint Verified. | | 16 Apr 2021 18:33:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Acute CVA' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:16:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:00 |
| DataPoint Verified. | | 16 Apr 2021 18:33:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Unknown' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:16:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:30:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:00 |
| DataPoint Verified. | | 16 Apr 2021 18:33:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Other (OTHER)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:16:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:30:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:00 |
| DataPoint Verified. | | 16 Apr 2021 18:33:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Unknown' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:16:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:30:59

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:00 |
| DataPoint Verified. | | 16 Apr 2021 18:33:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'once (ONCE)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:16:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:30:59

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:00 |
| DataPoint Verified. | | 16 Apr 2021 18:33:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:16:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:30:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:00 |
| DataPoint Verified. | | 16 Apr 2021 18:33:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Intravenous (INTRAVENOUS)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:16:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:30:59

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:00 |
| DataPoint Verified. | | 16 Apr 2021 18:33:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:16:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:00 |
| DataPoint Verified. | | 16 Apr 2021 18:33:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'un Oct 2020' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:16:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:00 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:16:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:00 |
| DataPoint Verified. | | 16 Apr 2021 18:33:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:16:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:00 |
| DataPoint Verified. | | 16 Apr 2021 18:33:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'un Oct 2020' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:16:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:30:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:00 |
| DataPoint Verified. | | 16 Apr 2021 18:33:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:16:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:30:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:00 |
| User entered empty. | System | 11 Feb 2021 15:16:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:00 |
| User entered empty. | System | 11 Feb 2021 15:16:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:00 |
| User entered empty. | System | 11 Feb 2021 15:16:13 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:30:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:04 |
| DataPoint Verified. | | 16 Apr 2021 18:33:33 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 03 Mar 2021 13:28:03 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 03 Mar 2021 13:28:03 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Feb 2021 14:10:39 |
| Data point term sent to Coder | System | 11 Feb 2021 15:19:54 |
| User entered 'Vancomycin' | (b) (4), (b) (6) | 11 Feb 2021 15:18:57 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:30:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:04 |
| DataPoint Verified. | | 16 Apr 2021 18:33:33 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:18:57 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:04 |
| DataPoint Verified. | | 16 Apr 2021 18:33:33 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Prophylaxis of Infection' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:18:57 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:04 |
| DataPoint Verified. | | 16 Apr 2021 18:33:33 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Unknown' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:18:57 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:30:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:04 |
| DataPoint Verified. | | 16 Apr 2021 18:33:33 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Other (OTHER)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:18:57 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:30:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:04 |
| DataPoint Verified. | | 16 Apr 2021 18:33:33 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Unknown' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:18:57 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:30:59

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:04 |
| DataPoint Verified. | | 16 Apr 2021 18:33:33 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'once (ONCE)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:18:57 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:30:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:04 |
| DataPoint Verified. | | 16 Apr 2021 18:33:33 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:18:57 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:30:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:04 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:33 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)' | (b) (4), (b) (6) | 11 Feb 2021 15:18:57 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:30:59

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:04 |
| DataPoint Verified. | | 16 Apr 2021 18:33:33 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:18:57 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:04 |
| DataPoint Verified. | | 16 Apr 2021 18:33:33 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'un Oct 2020' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:18:57 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:04 |
| DataPoint Verified. | | 16 Apr 2021 18:33:33 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:18:57 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:04 |
| DataPoint Verified. | | 16 Apr 2021 18:33:33 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:18:57 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:04 |
| DataPoint Verified. | | 16 Apr 2021 18:33:33 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'un Oct 2020' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:18:57 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:30:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:04 |
| DataPoint Verified. | | 16 Apr 2021 18:33:33 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:18:57 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:30:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:04 |
| User entered empty. | System | 11 Feb 2021 15:18:57 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:04 |
| User entered empty. | System | 11 Feb 2021 15:18:57 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:24:04 |
| User entered empty. | System | 11 Feb 2021 15:18:57 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:30:59

Name of Medication

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:58 |
| DataPoint Verified. | | 16 Apr 2021 18:33:07 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOPAMIDOL, PRODUCTSYNONYM: ISOVUE-370 - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 11 Feb 2021 15:21:53 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Feb 2021 15:21:53 |
| Data point term sent to Coder | System | 11 Feb 2021 15:20:55 |
| User entered 'Isovue-370' | (b) (4), (b) (6) | 11 Feb 2021 15:20:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:30:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:58 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:07 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 11 Feb 2021 15:20:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:58 |
| DataPoint Verified. | | 16 Apr 2021 18:33:07 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Acute CVA (CTA)' | (b) (4), (b) (6) | 11 Feb 2021 15:20:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:58 |
| DataPoint Verified. | | 16 Apr 2021 18:33:07 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '100' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:20:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:30:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:33:07 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'mL (mL)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:20:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:30:59

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:58 |
| DataPoint Verified. | | 16 Apr 2021 18:33:07 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:20:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:30:59

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:58 |
| DataPoint Verified. | | 16 Apr 2021 18:33:07 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'once (ONCE)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:20:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:30:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:58 |
| DataPoint Verified. | | 16 Apr 2021 18:33:07 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 15:20:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:30:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:58 |
| DataPoint Verified. | | 16 Apr 2021 18:33:07 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Intravenous (INTRAVENOUS)' | (b) (4), (b) (6) | 11 Feb 2021 15:20:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:30:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:58 |
| DataPoint Verified. | | 16 Apr 2021 18:33:07 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 15:20:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:58 |
| DataPoint Verified. | | 16 Apr 2021 18:33:07 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '25 Oct 2020' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:20:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:58 |
| DataPoint Verified. | | 16 Apr 2021 18:33:07 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 15:20:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:58 |
| DataPoint Verified. | | 16 Apr 2021 18:33:07 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:20:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:58 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:07 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '25 Oct 2020' | (b) (4), (b) (6) | 11 Feb 2021 15:20:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:30:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:58 |
| DataPoint Verified. | | 16 Apr 2021 18:33:07 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:20:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:30:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:58 |
| User entered empty. | System | 11 Feb 2021 15:20:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:58 |
| User entered empty. | System | 11 Feb 2021 15:20:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:58:58 |
| User entered empty. | System | 11 Feb 2021 15:20:23 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:30:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:02 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 22 Apr 2021 07:14:01 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 22 Apr 2021 07:14:01 |
| Data point term sent to Coder | System | 21 Apr 2021 20:38:52 |
| Coding entries removed. | Nathan Cortez (b) (4) | 21 Apr 2021 20:38:24 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 18 Apr 2021 14:02:46 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 18 Apr 2021 14:02:46 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:33:23 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 15 Mar 2021 15:17:59 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 15 Mar 2021 15:17:59 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Feb 2021 14:10:39 |
| Data point term sent to Coder | System | 11 Feb 2021 15:21:55 |
| User entered 'Sodium Chloride' | (b) (4), (b) (6) | 11 Feb 2021 15:21:25 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:30:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:02 |
| DataPoint Verified. | | 16 Apr 2021 18:33:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:21:25 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:02 |
| User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate. ' (Site from DM). DataPoint Verified. | (b) (4), (b) (6) | 23 Apr 2021 06:26:42 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Apr 2021 22:11:36 |
| Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate. ' answered with 'Updated in source and eCRF' (Site from DM). DataPoint Un-verified. | Nathan Cortez (b) (4) | 21 Apr 2021 20:38:36 |
| Signature has been broken. | Nathan Cortez (b) (4) | 21 Apr 2021 20:38:24 |
| User entered 'PROPHYLAXIS (Infection)' reason for change: Data Entry Error DataPoint Verified. | Nathan Cortez (b) (4) (b) (4), (b) (6) | 21 Apr 2021 20:38:24 |
| User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate. ' (Site from DM). User signature succeeded. | (b) (4), (b) (6) Douglas Denham (b) (4) (b) (4) | 16 Apr 2021 18:33:23 |
| User entered 'prophylaxis' | (b) (4), (b) (6) | 07 Apr 2021 05:15:11 |
| | Douglas Denham (b) (4) (b) (4) | 23 Feb 2021 14:10:39 |
| | (b) (4), (b) (6) | 11 Feb 2021 15:21:25 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:02 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '1000' | (b) (4), (b) (6) | 11 Feb 2021 15:21:25 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:30:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:02 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'mL (mL)' | (b) (4), (b) (6) | 11 Feb 2021 15:21:25 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:30:59

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:02 |
| DataPoint Verified. | | 16 Apr 2021 18:33:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:21:25 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:30:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:02 |
| DataPoint Verified. | | 16 Apr 2021 18:33:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'as needed (PRN)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:21:25 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:30:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:02 |
| DataPoint Verified. | | 16 Apr 2021 18:33:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:21:25 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:30:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:02 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Intravenous (INTRAVENOUS)' | (b) (4), (b) (6) | 11 Feb 2021 15:21:25 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:30:59

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:02 |
| DataPoint Verified. | | 16 Apr 2021 18:33:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:21:25 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:30:59

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:02 |
| DataPoint Verified. | | 16 Apr 2021 18:33:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '25 Oct 2020' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:21:25 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:02 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '0' | (b) (4), (b) (6) | 11 Feb 2021 15:21:25 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:02 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:33:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:21:25 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:02 |
| DataPoint Verified. | | 16 Apr 2021 18:33:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '29 Oct 2020' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:21:25 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:30:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:02 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 11 Feb 2021 15:21:25 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:30:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:02 |
| User entered empty. | System | 11 Feb 2021 15:21:25 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:02 |
| User entered empty. | System | 11 Feb 2021 15:21:25 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:02 |
| User entered empty. | System | 11 Feb 2021 15:21:25 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:30:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:08 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 05 Mar 2021 15:26:05 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Mar 2021 15:26:05 |
| Data point term sent to Coder | System | 05 Mar 2021 15:05:46 |
| User entered 'influenza vaccine' | Gerardo Pena (b) (4) | 05 Mar 2021 15:05:30 |
| | (b) (4) | |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:30:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:08 |
| DataPoint Verified. | (b) (4) | 16 Apr 2021 18:33:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'Yes (Y)' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:05:30 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:08 |
| DataPoint Verified. | | 16 Apr 2021 18:33:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'prophylaxis' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:05:30 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:08 |
| DataPoint Verified. | | 16 Apr 2021 18:33:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered '0.5' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:05:30 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:30:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:08 |
| DataPoint Verified. | | 16 Apr 2021 18:33:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'mL (mL)' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:05:30 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:30:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:08 |
| DataPoint Verified. | | 16 Apr 2021 18:33:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered empty. | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:05:30 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:30:59

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:08 |
| DataPoint Verified. | | 16 Apr 2021 18:33:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'once (ONCE)' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:05:30 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:30:59

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:08 |
| DataPoint Verified. | | 16 Apr 2021 18:33:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered empty. | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:05:30 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:30:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:08 |
| DataPoint Verified. | | 16 Apr 2021 18:33:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:05:30 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:30:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:08 |
| DataPoint Verified. | | 16 Apr 2021 18:33:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered empty. | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:05:30 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:30:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:08 |
| DataPoint Verified. | | 16 Apr 2021 18:33:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered '14 Nov 2020' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:05:30 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:08 |
| DataPoint Verified. | | 16 Apr 2021 18:33:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered '0' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:05:30 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:08 |
| DataPoint Verified. | | 16 Apr 2021 18:33:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'No (N)' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:05:30 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:08 |
| DataPoint Verified. | | 16 Apr 2021 18:33:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered '14 Nov 2020' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:05:30 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:30:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:08 |
| DataPoint Verified. | | 16 Apr 2021 18:33:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'No (N)' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:05:30 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:30:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:08 |
| User entered empty. | System | 05 Mar 2021 15:05:30 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:08 |
| User entered empty. | System | 05 Mar 2021 15:05:30 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:08 |
| User entered empty. | System | 05 Mar 2021 15:05:30 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:30:59

Name of Medication

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:32:53 |
| User closed query 'Per DM CLR: Con Med TESTOSTERONE was added/changed on 30 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM). | | 26 Mar 2021 09:04:10 |
| Query 'Per DM CLR: Con Med TESTOSTERONE was added/changed on 30 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'No worsening or exacerbation. Patient previously chose no therapy, but changed his mind. ' (Site from DM). | Antonio Gutierrez (b) (4) | 24 Mar 2021 17:23:13 |
| User opened query 'Per DM CLR: Con Med TESTOSTERONE was added/changed on 30 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM). | (b) (4), (b) (6) | 24 Mar 2021 11:02:21 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\202003. | (b) (4) Coder Import (b) (4) | 05 Mar 2021 15:26:08 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 05 Mar 2021 15:26:08 |
| Data point term sent to Coder | System | 05 Mar 2021 15:07:47 |
| User entered 'testosterone' | Gerardo Pena (b) (4) | 05 Mar 2021 15:06:47 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

2450 of 2656

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:30:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:32:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'No (N)' | (b) (4) Gerardo Pena (b) (4) | 05 Mar 2021 15:06:47 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:32:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'low testosterone' | (b) (4) Gerardo Pena (b) (4) | 05 Mar 2021 15:06:47 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:32:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'l' | (b) (4) Gerardo Pena (b) (4) | 05 Mar 2021 15:06:47 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:30:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:32:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'Other (OTHER)' | (b) (4) Gerardo Pena (b) (4) | 05 Mar 2021 15:06:47 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:30:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:32:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'CC' | (b) (4) Gerardo Pena (b) (4) | 05 Mar 2021 15:06:47 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:30:59

[Frequency](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:32:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System). | (b) (4) System | 05 Mar 2021 15:06:55 |
| User entered 'other (OTHER)' reason for change: Data Entry Error | Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:06:55 |
| User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System). | System | 05 Mar 2021 15:06:47 |
| User entered 'once (ONCE)' | Gerardo Pena (b) (4) (b) (4) | 05 Mar 2021 15:06:47 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:30:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:32:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'every other week' | (b) (4) Gerardo Pena (b) (4) | 05 Mar 2021 15:06:47 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:30:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:32:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4) Gerardo Pena (b) (4) | 05 Mar 2021 15:06:47 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:30:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:32:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered empty. | (b) (4) Gerardo Pena (b) (4) | 05 Mar 2021 15:06:47 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:30:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:32:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered '30 Oct 2020' | (b) (4) Gerardo Pena (b) (4) | 05 Mar 2021 15:06:47 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:32:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered '0' | (b) (4) Gerardo Pena (b) (4) | 05 Mar 2021 15:06:47 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:32:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'Yes (Y)' | (b) (4) Gerardo Pena (b) (4) | 05 Mar 2021 15:06:47 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:32:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered empty. | (b) (4) Gerardo Pena (b) (4) | 05 Mar 2021 15:06:47 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:30:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:32:53 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'No (N)' | (b) (4) Gerardo Pena (b) (4) | 05 Mar 2021 15:06:47 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:30:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Mar 2021 15:06:47 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Mar 2021 15:06:47 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Mar 2021 15:06:47 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:30:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:32:50 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: ENZYMES, PRODUCT: ALTEPLASE, PRODUCTSYNONYM: ACTIVASE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 25 Mar 2021 11:28:26 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 25 Mar 2021 11:28:26 |
| Data point term sent to Coder | System | 24 Mar 2021 20:11:09 |
| User entered 'Alteplase/Activase' | Antonio Gutierrez (b) (4) | 24 Mar 2021 20:10:58 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:30:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 18:32:50 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 24 Mar 2021 20:10:58 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 18:32:50 |
| User entered 'Stroke' | Antonio Gutierrez (b) (4) | 24 Mar 2021 20:10:58 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:30:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:13 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:32:50 |
| User closed query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available. Please review and update accordingly' (Site from DM). | | 16 Apr 2021 09:35:55 |
| Query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available. Please review and update accordingly' answered with 'updated' (Site from DM). | Dawn Killian (b) (4) (b) (4) | 15 Apr 2021 15:30:36 |
| User entered 'UNK' reason for change: Data Entry Error | Dawn Killian (b) (4) (b) (4) | 15 Apr 2021 15:30:32 |
| User opened query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available. Please review and update accordingly' (Site from DM). | (b) (4), (b) (6) | 05 Apr 2021 11:07:41 |
| User entered 'UNKNOWN' | Antonio Gutierrez (b) (4) | 24 Mar 2021 20:10:58 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:30:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 18:32:50 |
| User entered 'Other (OTHER)' | Antonio Gutierrez (b) (4) | 24 Mar 2021 20:10:58 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:30:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:32:50 |
| User entered 'UNKNOWN' | Antonio Gutierrez (b) (4) | 24 Mar 2021 20:10:58 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:30:59

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 18:32:50 |
| User entered 'once (ONCE)' | Antonio Gutierrez (b) (4) | 24 Mar 2021 20:10:58 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:30:59

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 18:32:50 |
| User entered empty. | Antonio Gutierrez (b) (4) | 24 Mar 2021 20:10:58 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:30:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 18:32:50 |
| User entered 'Intravenous (INTRAVENOUS)' | Antonio Gutierrez (b) (4) | 24 Mar 2021 20:10:58 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:30:59

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 18:32:50 |
| User entered empty. | Antonio Gutierrez (b) (4) | 24 Mar 2021 20:10:58 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:30:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:32:50 |
| User entered '25 Oct 2020' | Antonio Gutierrez (b) (4) | 24 Mar 2021 20:10:58 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:30:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:32:50 |
| User entered '0' | Antonio Gutierrez (b) (4) | 24 Mar 2021 20:10:58 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:30:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 18:32:50 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 24 Mar 2021 20:10:58 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:30:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:32:50 |
| User entered '25 Oct 2020' | Antonio Gutierrez (b) (4) | 24 Mar 2021 20:10:58 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:30:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:13 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:32:50 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 24 Mar 2021 20:10:58 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:30:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:13 |
| User entered empty. | System | 24 Mar 2021 20:10:58 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:13 |
| User entered empty. | System | 24 Mar 2021 20:10:58 |

US3292312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:30:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:59:13 |
| User entered empty. | System | 24 Mar 2021 20:10:58 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:30:59

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 05:13:31 |
| DataPoint Verified. | | 05 Apr 2021 21:09:48 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Yes (Y)' | (b) (4) Victoria Hernandez (b) (4) | 06 Nov 2020 17:22:19 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:30:59

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:36:41 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '25 Oct 2020' | (b) (4), (b) (6) | 11 Feb 2021 15:22:51 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:30:59

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:36:41 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'CTA-Head and Neck' | (b) (4), (b) (6) | 11 Feb 2021 15:22:51 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:36:41 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error | (b) (4) | 11 Feb 2021 15:23:29 |
| User entered 'Adverse Event (AE)' | (b) (4), (b) (6) | 11 Feb 2021 15:22:51 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:30:59

If indication is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:36:41 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:22:51 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:30:59

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:36:51 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '26 Oct 2020' | (b) (4), (b) (6) | 11 Feb 2021 15:23:10 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:30:59

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:36:51 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'MRI' | (b) (4), (b) (6) | 11 Feb 2021 15:23:10 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:36:51 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error | (b) (4) | 11 Feb 2021 15:23:16 |
| User entered 'Adverse Event (AE)' | (b) (4), (b) (6) | 11 Feb 2021 15:23:10 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:30:59

[If indication is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:36:51 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:23:10 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:30:59

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:37:00 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '27 Oct 2020' | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:24:00 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:30:59

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:37:00 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Carotid Doppler' | (b) (4), (b) (6) | 11 Feb 2021 15:24:00 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:37:00 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Diagnostic (DIAGNOSTIC)' | (b) (4), (b) (6) | 11 Feb 2021 15:24:00 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:30:59

If indication is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:37:00 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 15:24:00 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:30:59

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:37:04 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '26 Oct 2020' | (b) (4), (b) (6) | 11 Feb 2021 15:24:23 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:30:59

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:37:04 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Head CT' | (b) (4), (b) (6) | 11 Feb 2021 15:24:23 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:37:04 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Diagnostic (DIAGNOSTIC)' | (b) (4), (b) (6) | 11 Feb 2021 15:24:23 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:30:59

If indication is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:37:04 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 15:24:23 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:30:59

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:37:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '25 Oct 2020' | (b) (4), (b) (6) | 11 Feb 2021 15:24:42 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:30:59

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:37:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Head CT' | (b) (4), (b) (6) | 11 Feb 2021 15:24:42 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:37:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'Diagnostic (DIAGNOSTIC)' | (b) (4), (b) (6) | 11 Feb 2021 15:24:42 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:30:59

If indication is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:37:06 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered empty. | (b) (4), (b) (6) | 11 Feb 2021 15:24:42 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:30:59

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:37:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered '30 Dec 2020' | (b) (4) Gerardo Pena (b) (4) | 05 Mar 2021 15:09:58 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:30:59

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|-------------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:37:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'AICD Insertion' | (b) (4) Gerardo Pena (b) (4) | 05 Mar 2021 15:09:58 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:37:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| User closed query 'Per DM CLR: Please review the indication = DIAGNOSTIC as the recorded procedure is therapeutic in nature and not being done for diagnostic purposes. Please confirm if procedure is done for a MedHistory or AE condition and update as appropriate, otherwise provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 22 Mar 2021 15:24:40 |
| Query 'Per DM CLR: Please review the indication = DIAGNOSTIC as the recorded procedure is therapeutic in nature and not being done for diagnostic purposes. Please confirm if procedure is done for a MedHistory or AE condition and update as appropriate, otherwise provide clarification. ' answered with 'updated' (Site from DM). | Antonio Gutierrez (b) (4) | 19 Mar 2021 18:10:19 |
| Signature has been broken. | Antonio Gutierrez (b) (4) | 19 Mar 2021 18:10:03 |
| User entered 'Adverse Event (AE)' reason for change: Per Query Resolution | Antonio Gutierrez (b) (4) | 19 Mar 2021 18:10:03 |
| User opened query 'Per DM CLR: Please review the indication = DIAGNOSTIC as the recorded procedure is therapeutic in nature and not being done for diagnostic purposes. Please confirm if procedure is done for a MedHistory or AE condition and update as appropriate, otherwise provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 19 Mar 2021 12:15:25 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered 'Diagnostic (DIAGNOSTIC)' | Gerardo Pena (b) (4) | 05 Mar 2021 15:09:58 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:30:59

If indication is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:37:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:08:26 |
| User entered empty. | (b) (4) Gerardo Pena (b) (4) | 05 Mar 2021 15:09:58 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:30:59

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:37:18 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| User entered '25 Oct 2020' | (b) (4) Dawn Killian (b) (4) | 23 Mar 2021 19:08:48 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:30:59

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:37:18 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| User entered 'chest x-ray' | (b) (4) Dawn Killian (b) (4) | 23 Mar 2021 19:08:48 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:37:18 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| User entered 'Diagnostic (DIAGNOSTIC)' | (b) (4) Dawn Killian (b) (4) | 23 Mar 2021 19:08:48 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:30:59

If indication is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:37:18 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| User entered empty. | (b) (4) Dawn Killian (b) (4) | 23 Mar 2021 19:08:48 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 16:30:59

Procedure/Surgery date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:37:33 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| User entered '28 Oct 2020' | (b) (4) Dawn Killian (b) (4) | 23 Mar 2021 19:09:12 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 16:30:59

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:37:33 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| User entered 'transesophageal' | (b) (4) Dawn Killian (b) (4) | 23 Mar 2021 19:09:12 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:37:33 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| User entered 'Diagnostic (DIAGNOSTIC)' | (b) (4) Dawn Killian (b) (4) | 23 Mar 2021 19:09:12 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 16:30:59

If indication is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 18:37:33 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| User entered empty. | (b) (4) Dawn Killian (b) (4) | 23 Mar 2021 19:09:12 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 16:30:59

Procedure/Surgery date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 28 Apr 2021 13:40:24 |
| User closed query 'Per med rec date of study was 26OCT20.p.17of41. Please confirm and update.' (Site from CRA). | (b) (4), (b) (6) | 23 Apr 2021 19:06:21 |
| DataPoint Verified. | | 23 Apr 2021 19:06:19 |
| Query 'Per med rec date of study was 26OCT20.p.17of41. Please confirm and update.' answered with 'updated as per med rec' (Site from CRA). | Antonio Gutierrez (b) (4) | 23 Apr 2021 18:59:03 |
| Signature has been broken. | Antonio Gutierrez (b) (4) | 23 Apr 2021 18:58:52 |
| User entered '26 Oct 2020' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 23 Apr 2021 18:58:52 |
| User opened query 'Per med rec date of study was 26OCT20.p.17of41. Please confirm and update.' (Site from CRA). | (b) (4), (b) (6) | 23 Apr 2021 18:51:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| User entered '28 Oct 2020' | Nathan Cortez (b) (4) | 21 Apr 2021 18:20:27 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 16:30:59

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|-------------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Apr 2021 18:51:26 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| User entered 'Echocardiogram' | (b) (4) Nathan Cortez (b) (4) | 21 Apr 2021 18:20:27 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 16:30:59

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Apr 2021 18:51:27 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| User entered 'Adverse Event (AE)' | (b) (4) Nathan Cortez (b) (4) | 21 Apr 2021 18:20:27 |

US3292312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 16:30:59

If indication is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Apr 2021 18:51:28 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:24 |
| User entered empty. | (b) (4) Nathan Cortez (b) (4) | 21 Apr 2021 18:20:27 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'USA-US072-2020-MRNA-1273-P301000006' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Yes (Y)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Yes (Y)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Douglas' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Denham' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered '7940 Floyd Curl Drive' | | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'San Antonio' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered '78229' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'US' | | 27 Oct 2020 14:25:04 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User entered '7' | System | 25 Mar 2021 13:07:47 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| | (b) (4) | |
| User entered '6' | System | 12 Feb 2021 14:26:14 |
| User entered '5' | System | 10 Feb 2021 15:11:35 |
| User entered '4' | System | 14 Jan 2021 15:14:41 |
| User entered '3' | System | 25 Nov 2020 19:56:34 |
| User entered '2' | System | 28 Oct 2020 14:47:08 |
| User entered '1' | System | 27 Oct 2020 14:25:04 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'USA-US072-2020-MRNA-1273-P301000006' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Yes (Y)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 8 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Yes (Y)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Douglas' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Denham' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered '7940 Floyd Curl Drive' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'San Antonio' | | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered '78229' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'US' | System | 27 Oct 2020 14:25:04 |

US3292312

Folder: SAE-USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User entered '7' | System | 25 Mar 2021 13:07:47 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| | (b) (4) | |
| User entered '6' | System | 12 Feb 2021 14:26:14 |
| User entered '5' | System | 10 Feb 2021 15:11:35 |
| User entered '4' | System | 14 Jan 2021 15:14:41 |
| User entered '3' | System | 25 Nov 2020 19:56:34 |
| User entered '2' | System | 28 Oct 2020 14:47:08 |
| User entered '1' | System | 27 Oct 2020 14:25:04 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:30:59

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:10:19 |
| User entered '27/Oct/2020 14:25' | System | 27 Oct 2020 14:25:04 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:30:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'l' | | 27 Oct 2020 14:25:04 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'USA-US072-2020-MRNA-1273-P301000006' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Yes (Y)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Yes (Y)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Douglas' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Denham' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered '7940 Floyd Curl Drive' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'San Antonio' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered '78229' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'US' | System | 27 Oct 2020 14:25:04 |

US3292312

Folder: SAE-USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User entered '7' | System | 25 Mar 2021 13:07:47 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| | (b) (4) | |
| User entered '6' | System | 12 Feb 2021 14:26:14 |
| User entered '5' | System | 10 Feb 2021 15:11:35 |
| User entered '4' | System | 14 Jan 2021 15:14:41 |
| User entered '3' | System | 25 Nov 2020 19:56:34 |
| User entered '2' | System | 28 Oct 2020 14:47:08 |
| User entered '1' | System | 27 Oct 2020 14:25:04 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:30:59

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 23:10:19 |
| User entered '28/Oct/2020 10:47' | System | 28 Oct 2020 14:47:08 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:30:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| Reviewed for Safety. | (b) (4) | 14 Jan 2021 15:14:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Nov 2020 23:10:19 |
| User entered 'l' | | 28 Oct 2020 14:47:08 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'USA-US072-2020-MRNA-1273-P301000006' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Yes (Y)' | | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Yes (Y)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Douglas' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Denham' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered '7940 Floyd Curl Drive' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'San Antonio' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered '78229' | | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'US' | System | 27 Oct 2020 14:25:04 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User entered '7' | System | 25 Mar 2021 13:07:47 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| | (b) (4) | |
| User entered '6' | System | 12 Feb 2021 14:26:14 |
| User entered '5' | System | 10 Feb 2021 15:11:35 |
| User entered '4' | System | 14 Jan 2021 15:14:41 |
| User entered '3' | System | 25 Nov 2020 19:56:34 |
| User entered '2' | System | 28 Oct 2020 14:47:08 |
| User entered '1' | System | 27 Oct 2020 14:25:04 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:30:59

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 18 Jan 2021 19:40:07 |
| User entered '25/Nov/2020 14:56' | System | 25 Nov 2020 19:56:34 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:30:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 18 Jan 2021 19:40:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Jan 2021 15:14:30 |
| User entered 'l' | | 25 Nov 2020 19:56:34 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'USA-US072-2020-MRNA-1273-P301000006' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Yes (Y)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Yes (Y)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Douglas' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Denham' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered '7940 Floyd Curl Drive' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'San Antonio' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered '78229' | | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'US' | System | 27 Oct 2020 14:25:04 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User entered '7' | System | 25 Mar 2021 13:07:47 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| | (b) (4) | |
| User entered '6' | System | 12 Feb 2021 14:26:14 |
| User entered '5' | System | 10 Feb 2021 15:11:35 |
| User entered '4' | System | 14 Jan 2021 15:14:41 |
| User entered '3' | System | 25 Nov 2020 19:56:34 |
| User entered '2' | System | 28 Oct 2020 14:47:08 |
| User entered '1' | System | 27 Oct 2020 14:25:04 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:30:59

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 18 Jan 2021 19:40:12 |
| User entered '14/Jan/2021 10:14' | System | 14 Jan 2021 15:14:41 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:30:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 18 Jan 2021 19:40:13 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Jan 2021 15:14:47 |
| User entered 'l' | | 14 Jan 2021 15:14:41 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'USA-US072-2020-MRNA-1273-P301000006' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Yes (Y)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Yes (Y)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Douglas' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | | 28 Oct 2020 14:46:59 |
| User entered 'Denham' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered '7940 Floyd Curl Drive' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'San Antonio' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered '78229' | | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'US' | System | 27 Oct 2020 14:25:04 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User entered '7' | System | 25 Mar 2021 13:07:47 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| | (b) (4) | |
| User entered '6' | System | 12 Feb 2021 14:26:14 |
| User entered '5' | System | 10 Feb 2021 15:11:35 |
| User entered '4' | System | 14 Jan 2021 15:14:41 |
| User entered '3' | System | 25 Nov 2020 19:56:34 |
| User entered '2' | System | 28 Oct 2020 14:47:08 |
| User entered '1' | System | 27 Oct 2020 14:25:04 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:30:59

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:37:35 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '10/Feb/2021 09:11' | (b) (4) System | 10 Feb 2021 15:11:35 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:30:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:37:35 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Feb 2021 14:10:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 12 Feb 2021 14:25:56 |
| User entered 'l' | | 10 Feb 2021 15:11:35 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'USA-US072-2020-MRNA-1273-P301000006' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Yes (Y)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

Death

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Yes (Y)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Douglas' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Denham' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered '7940 Floyd Curl Drive' | | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'San Antonio' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered '78229' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'US' | System | 27 Oct 2020 14:25:04 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User entered '7' | System | 25 Mar 2021 13:07:47 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| | (b) (4) | |
| User entered '6' | System | 12 Feb 2021 14:26:14 |
| User entered '5' | System | 10 Feb 2021 15:11:35 |
| User entered '4' | System | 14 Jan 2021 15:14:41 |
| User entered '3' | System | 25 Nov 2020 19:56:34 |
| User entered '2' | System | 28 Oct 2020 14:47:08 |
| User entered '1' | System | 27 Oct 2020 14:25:04 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:30:59

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:37:34 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered '12/Feb/2021 14:26' | (b) (4) System | 12 Feb 2021 14:26:14 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:30:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:37:34 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Mar 2021 13:07:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| User entered 'l' | (b) (4), (b) (6) | 12 Feb 2021 14:26:14 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'USA-US072-2020-MRNA-1273-P301000006' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Yes (Y)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Yes (Y)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'No (N)' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Douglas' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'Denham' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered '7940 Floyd Curl Drive' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'San Antonio' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered '78229' | System | 27 Oct 2020 14:24:29 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| DataPoint Verified. | (b) (4) | 04 Nov 2020 23:10:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 14:46:59 |
| User entered 'US' | System | 27 Oct 2020 14:25:04 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User entered '7' | System | 25 Mar 2021 13:07:47 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:10:39 |
| | (b) (4) | |
| User entered '6' | System | 12 Feb 2021 14:26:14 |
| User entered '5' | System | 10 Feb 2021 15:11:35 |
| User entered '4' | System | 14 Jan 2021 15:14:41 |
| User entered '3' | System | 25 Nov 2020 19:56:34 |
| User entered '2' | System | 28 Oct 2020 14:47:08 |
| User entered '1' | System | 27 Oct 2020 14:25:04 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:30:59

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 20:37:31 |
| User entered '25/Mar/2021 09:07' | System | 25 Mar 2021 13:07:47 |

US3292312

Folder: SAE USA-US072-2020-MRNA-1273-P301000006

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:30:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:40:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:37:31 |
| User entered 'I' | | 25 Mar 2021 13:07:47 |