

US3292245 (Prod: Clinical Trials of Texas, Inc)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:27:53

All time stamps listed in this document are displayed in GMT

US3292245

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

[Participant ID](#)

US3292245

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

US3292245

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 21:18:16

Generated On: 09 Jun 2021 16:27:53

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 20 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | SCRN |

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1952 |
| Age | 67 |
| Age Units | YEARS |
| Age (Derived) | 67 |
| 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) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Feb 2021 21:18:15

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 21:18:15

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

| | |
|---|--|
| Condition | STENT PLACEMENT - X3 |
| Start date (dd MMM yyyy) | UN MAY 2016 |
| 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 MAY 2016 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | MAY 2016 |
| Start Year (derived) | 2016 |
| Stop Month and Year (derived) | MAY 2016 |
| Stop Year (derived) | 2016 |

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Feb 2021 21:18:15

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| | |
|---|--|
| Condition | STENT PLACEMENT - X1 |
| Start date (dd MMM yyyy) | 09 JAN 2018 |
| 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) | 09 JAN 2018 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2018 |
| Start Year (derived) | 2018 |
| Stop Month and Year (derived) | JAN 2018 |
| Stop Year (derived) | 2018 |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

| | |
|---|--|
| Condition | MYOCARDIAL INFARCTION |
| Start date (dd MMM yyyy) | UN MAY 2016 |
| 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 MAY 2016 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | MAY 2016 |
| Start Year (derived) | 2016 |
| Stop Month and Year (derived) | MAY 2016 |
| Stop Year (derived) | 2016 |

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Feb 2021 21:18:15

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| | |
|---|--|
| Condition | MYOCARDIAL INFARCTION |
| Start date (dd MMM yyyy) | 09 JAN 2018 |
| 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) | 09 JAN 2018 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2018 |
| Start Year (derived) | 2018 |
| Stop Month and Year (derived) | JAN 2018 |
| Stop Year (derived) | 2018 |

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

| | |
|---|--|
| Condition | HYPERLIPIDEMIA |
| 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 (6)

Data signed: (b) (4) 22 Feb 2021 21:18:15

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| | |
|---|--|
| Condition | CHRONIC BACK PAIN |
| Start date (dd MMM yyyy) | UN UNK 1990 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1990 |
| Start Year (derived) | 1990 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 22 Feb 2021 21:18:15

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| | |
|---|--|
| Condition | VITILIGO |
| 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 (8)

Data signed: (b) (4) 22 Feb 2021 21:18:15

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| | |
|---|--|
| Condition | HYPERTENSION |
| Start date (dd MMM yyyy) | UN MAY 2016 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | MAY 2016 |
| Start Year (derived) | 2016 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 21:18:16

Generated On: 09 Jun 2021 16:27:53

| | |
|-------------------------------------|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 20 AUG 2020 |
| Time of assessment (00:00-23:59) | 11:21 (24 HR) |
| Vital Signs Date and Time (derived) | 20 AUG 2020 11:21 |
| Height (xxx.x) | 175.0 cm |
| Weight (xxx.x) | 79.3 kg |
| BMI (xxx.x) | 25.89388 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) 22 Feb 2021 21:18:15

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 21:18:15

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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

REAL ESTATE AGENT

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) 22 Feb 2021 21:18:15

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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) 22 Feb 2021 21:18:16

Generated On: 09 Jun 2021 16:27:53

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 20 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT1 |

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 22 Feb 2021 21:18:16

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

What was the participant's randomization number? 187344

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) 22 Feb 2021 21:18:16

Generated On: 09 Jun 2021 16:27:53

| | |
|--------|---------------|
| 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) 22 Feb 2021 21:18:16

Generated On: 09 Jun 2021 16:27:53

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 20 AUG 2020 |
| Time of assessment (00:00-23:59) | 11:17 (24 HR) |
| Vital Signs Date and Time (derived) | 20 AUG 2020 11:17 |
| 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) | 67 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 20 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 120 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 82 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 21:18:16

Generated On: 09 Jun 2021 16:27:53

| | |
|-------------------------------------|---|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/> |
| Were vital signs assessed? | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| Date of assessment (dd MMM yyyy) | 20 AUG 2020 |
| Time of assessment (00:00-23:59) | 13:16 (24 HR) |
| Vital Signs Date and Time (derived) | 20 AUG 2020 13:16 |
| Temperature (xxx.x) | 36.2 C |
| Route of measurement | Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 57 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 115 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 77 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 21:18:16

Generated On: 09 Jun 2021 16:27:53

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) 22 Feb 2021 21:18:16

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Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 12:46 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 12:46

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) 22 Feb 2021 21:18:16

Generated On: 09 Jun 2021 16:27:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 AUG 2020

Collection time (00:00-23:59)

11:55 (24 HR)

Collection date and time (derived)

20 AUG 2020 11:55

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 21:18:16

Generated On: 09 Jun 2021 16:27:53

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 20 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 11:45 | 20 AUG 2020 11:45 |
| Nasopharyngeal Swab 2 | No | | |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:18:16

Generated On: 09 Jun 2021 16:27:53

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 16:27:53

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

20 AUG 2020 13:20

PC Open Date & Time

20 AUG 2020 13:06

PC Close Date & Time

20 AUG 2020 15:36

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

99.0 °F

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

Yes ☐
No ☒

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 20 AUG 2020 20:15 |
| PC Open Date & Time | 20 AUG 2020 16:31 |
| PC Close Date & Time | 21 AUG 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:53

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

21 AUG 2020 21:05

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

22 AUG 2020 21:11

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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 AUG 2020 23:31

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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 AUG 2020 20:01

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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 00:02

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

26 AUG 2020 21:35

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 13:21

PC Open Date & Time

20 AUG 2020 13:06

PC Close Date & Time

20 AUG 2020 15:36

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

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

20 AUG 2020 20:16

PC Open Date & Time

20 AUG 2020 16:31

PC Close Date & Time

21 AUG 2020 11:59

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 21:06

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 21:12

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 21:52

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 20:02

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:53

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

26 AUG 2020 00:02

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 21:35

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

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 ☐

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 20 AUG 2020 13:21 |
| PC Open Date & Time | 20 AUG 2020 13:06 |
| PC Close Date & Time | 20 AUG 2020 15:36 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

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 ☐

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 20 AUG 2020 20:17 |
| PC Open Date & Time | 20 AUG 2020 16:31 |
| PC Close Date & Time | 21 AUG 2020 11:59 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

49 of 1967

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 21 AUG 2020 21:06 |
| PC Open Date & Time | 21 AUG 2020 12:00 |
| PC Close Date & Time | 22 AUG 2020 11:59 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

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

51 of 1967

EAB) (1725)

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 22 AUG 2020 21:12 |
| PC Open Date & Time | 22 AUG 2020 12:00 |
| PC Close Date & Time | 23 AUG 2020 11:59 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

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 ☒

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 23 AUG 2020 21:54 |
| PC Open Date & Time | 23 AUG 2020 12:00 |
| PC Close Date & Time | 24 AUG 2020 11:59 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

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)

55 of 1967

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 24 AUG 2020 20:02 |
| PC Open Date & Time | 24 AUG 2020 12:00 |
| PC Close Date & Time | 25 AUG 2020 11:59 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

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

57 of 1967

EAB) (1725)

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 26 AUG 2020 00:02 |
| PC Open Date & Time | 25 AUG 2020 12:00 |
| PC Close Date & Time | 26 AUG 2020 11:59 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

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

59 of 1967

EAB) (1725)

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 26 AUG 2020 21:36 |
| PC Open Date & Time | 26 AUG 2020 12:00 |
| PC Close Date & Time | 27 AUG 2020 11:59 |

US3292245

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292245

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292245

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292245

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292245

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292245

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292245

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 21:18:20

Generated On: 09 Jun 2021 16:27:53

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 17 SEP 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT2 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 21:18:20

Generated On: 09 Jun 2021 16:27:53

| | |
|-------------------------------------|---|
| Timepoint | Pre-Dose <input checked="" type="radio"/> |
| | Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 17 SEP 2020 |
| Time of assessment (00:00-23:59) | 09:44 (24 HR) |
| Vital Signs Date and Time (derived) | 17 SEP 2020 09:44 |
| Temperature (xxx.x) | 36.6 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 70 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 12 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 120 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 74 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 21:18:20

Generated On: 09 Jun 2021 16:27:53

| | |
|-------------------------------------|---|
| Timepoint | Pre-Dose <input type="checkbox"/> |
| | Post-Dose <input checked="" type="checkbox"/> |
| Were vital signs assessed? | Yes <input checked="" type="checkbox"/> |
| | No <input type="checkbox"/> |
| Date of assessment (dd MMM yyyy) | 17 SEP 2020 |
| Time of assessment (00:00-23:59) | 11:30 (24 HR) |
| Vital Signs Date and Time (derived) | 17 SEP 2020 11:30 |
| Temperature (xxx.x) | 36.4 C |
| Route of measurement | Oral <input checked="" type="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 64 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 12 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 111 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 73 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 21:18:20

Generated On: 09 Jun 2021 16:27:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

US3292245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 21:18:16

Generated On: 09 Jun 2021 16:27:53

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 17 SEP 2020

What was the treatment time? (00:00-23:59) 11:00 (24 HR)

Treatment Date and Time (derived) 17 SEP 2020 11:00

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

US3292245

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 21:18:20

Generated On: 09 Jun 2021 16:27:53

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 17 SEP 2020 |
| Collection time (00:00-23:59) | 10:00 (24 HR) |
| Collection date and time (derived) | 17 SEP 2020 10:00 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 21:18:16

Generated On: 09 Jun 2021 16:27:53

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 17 SEP 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 10:04 | 17 SEP 2020 10:04 |
| Nasopharyngeal Swab 2 | No | | |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:18:16

Generated On: 09 Jun 2021 16:27:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 11:29

PC Open Date & Time

17 SEP 2020 11:20

PC Close Date & Time

17 SEP 2020 13:50

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.5 °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 | 17 SEP 2020 20:51 |
| PC Open Date & Time | 17 SEP 2020 14:45 |
| PC Close Date & Time | 18 SEP 2020 11:59 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:53

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 100.3 °F

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

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

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

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

PC Time Stamp 18 SEP 2020 20:15

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

20 SEP 2020 00:02

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 23:22

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

21 SEP 2020 23:45

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

22 SEP 2020 20:15

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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 23:38

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

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

17 SEP 2020 11:29

PC Open Date & Time

17 SEP 2020 11:20

PC Close Date & Time

17 SEP 2020 13:50

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 20:52

PC Open Date & Time

17 SEP 2020 14:45

PC Close Date & Time

18 SEP 2020 11:59

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 20:16

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:53

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

20 SEP 2020 00:03

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 23:22

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 23:46

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 20:15

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 23:38

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

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 ☐

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 17 SEP 2020 11:30 |
| PC Open Date & Time | 17 SEP 2020 11:20 |
| PC Close Date & Time | 17 SEP 2020 13:50 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

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 ☐

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 17 SEP 2020 20:53 |
| PC Open Date & Time | 17 SEP 2020 14:45 |
| PC Close Date & Time | 18 SEP 2020 11:59 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

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 ☒

PRODUCTION RELEASE (v12.003

95 of 1967

EAB) (1725)

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 18 SEP 2020 20:16 |
| PC Open Date & Time | 18 SEP 2020 12:00 |
| PC Close Date & Time | 19 SEP 2020 11:59 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

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

97 of 1967

EAB) (1725)

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 20 SEP 2020 00:03 |
| PC Open Date & Time | 19 SEP 2020 12:00 |
| PC Close Date & Time | 20 SEP 2020 11:59 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

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

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EAB) (1725)

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 20 SEP 2020 23:23 |
| PC Open Date & Time | 20 SEP 2020 12:00 |
| PC Close Date & Time | 21 SEP 2020 11:59 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 21 SEP 2020 23:46 |
| PC Open Date & Time | 21 SEP 2020 12:00 |
| PC Close Date & Time | 22 SEP 2020 11:59 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

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

103 of 1967

EAB) (1725)

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 22 SEP 2020 20:15 |
| PC Open Date & Time | 22 SEP 2020 12:00 |
| PC Close Date & Time | 23 SEP 2020 11:59 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

105 of 1967

EAB) (1725)

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 23 SEP 2020 23:38 |
| PC Open Date & Time | 23 SEP 2020 12:00 |
| PC Close Date & Time | 24 SEP 2020 11:59 |

US3292245

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292245

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292245

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292245

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292245

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 OCT 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

THREE ATTEMPTS WERE MADE
TO CONTACT SUBJECT, NO
ANSWER, VISIT WAS NOT DONE

If Contact Not Made, please provide Comments

US3292245

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292245

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 21:18:20

Generated On: 09 Jun 2021 16:27:53

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 15 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 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 21:18:20

Generated On: 09 Jun 2021 16:27:53

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 15 OCT 2020 |
| Time of assessment (00:00-23:59) | 12:17 (24 HR) |
| Vital Signs Date and Time (derived) | 15 OCT 2020 12:17 |
| Temperature (xxx.x) | 36.6 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 69 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 12 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 104 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 63 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 21:18:20

Generated On: 09 Jun 2021 16:27:53

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.

US3292245

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 21:18:20

Generated On: 09 Jun 2021 16:27:53

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 15 OCT 2020 |
| Collection time (00:00-23:59) | 12:25 (24 HR) |
| Collection date and time (derived) | 15 OCT 2020 12:25 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:18:20

Generated On: 09 Jun 2021 16:27:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| | |
|---|--|
| 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 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 OCT 2020 13:18:28 |
| Patient Cloud Open Date & Time | 20 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 24 OCT 2020 23:59 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 OCT 2020 22:21:48

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| TIMEPOINT | DAY 78 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature \geq 100.4°F/38°C) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| TIMEPOINT | DAY 92 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 17 NOV 2020 00:02:56 |
| Patient Cloud Open Date & Time | 17 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 21 NOV 2020 23:59 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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 | 25 NOV 2020 14:45:58 |
| Patient Cloud Open Date & Time | 21 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 25 NOV 2020 23:59 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

28 NOV 2020 11:30:40

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 DEC 2020 00:01:44

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 DEC 2020 21:03:49

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 20:07:10

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

29 DEC 2020 21:41:39

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 138

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| TIMEPOINT | DAY 145 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

[Patient Cloud Close Date & Time](#)

13 JAN 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 13:04:29

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 JAN 2021 15:59:12

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 23:20:42

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 00:58:43

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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 | 16 FEB 2021 11:08:59 |
| Patient Cloud Open Date & Time | 13 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 17 FEB 2021 23:59 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 00:50:20

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

[Patient Cloud Close Date & Time](#)

17 MAR 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

20 MAR 2021 11:33:29

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| TIMEPOINT | DAY 222 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

[Patient Cloud Close Date & Time](#)

31 MAR 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| TIMEPOINT | DAY 229 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 18:11:30

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 APR 2021 00:01 |
| Patient Cloud Close Date & Time | 21 APR 2021 23:59 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| TIMEPOINT | DAY 278 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| TIMEPOINT | DAY 313 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 26 JUN 2021 00:01 |
| Patient Cloud Close Date & Time | 30 JUN 2021 23:59 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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="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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| TIMEPOINT | DAY 334 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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 ☐

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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 <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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 11 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 15 SEP 2021 23:59 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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 <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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 11 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 15 DEC 2021 23:59 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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 ☐

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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 ☐

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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 ☐

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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 ☐

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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 ☐

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| TIMEPOINT | DAY 544 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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 ☐

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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 <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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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 ☐

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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 ☐

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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 ☐

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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 ☐

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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 ☐

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 02 APR 2022 00:01 |
| Patient Cloud Close Date & Time | 06 APR 2022 23:59 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 16 APR 2022 00:01 |
| Patient Cloud Close Date & Time | 20 APR 2022 23:59 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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 ☐

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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 ☐

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 02 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 06 JUL 2022 23:59 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 09 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 13 JUL 2022 23:59 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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 ☐

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| TIMEPOINT | DAY 705 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

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24 AUG 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 03 SEP 2022 00:01 |
| Patient Cloud Close Date & Time | 07 SEP 2022 23:59 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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 ☐

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| TIMEPOINT | DAY 761 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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 ☐

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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="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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

| 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"/> |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

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

US3292245

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:27:53

| 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 | | 10 MAR 2021 12:15:09 |

US3292245

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3292245

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292245

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292245

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292245

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292245

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292245

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 FEB 2021

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

Comments 3 ATTEMPTS NO ANSWER

If Contact Not Made, please provide Comments

US3292245

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292245

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 15:49:02

Generated On: 09 Jun 2021 16:27:53

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT4

US3292245

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Apr 2021 15:49:02

Generated On: 09 Jun 2021 16:27:53

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) _____

US3292245

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 15:49:02

Generated On: 09 Jun 2021 16:27:53

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.

US3292245

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Apr 2021 15:49:02

Generated On: 09 Jun 2021 16:27:53

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3292245

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 15:49:02

Generated On: 09 Jun 2021 16:27:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292245

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 15:49:02

Generated On: 09 Jun 2021 16:27:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292245

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 15:49:02

Generated On: 09 Jun 2021 16:27:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292245

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

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

US3292245

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3292245

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:27:53

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

US3292245

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:27:53

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3292245

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

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 28 JAN 2021 |
|--------------------------|-------------|

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

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

US3292245

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 14:19:34

Generated On: 09 Jun 2021 16:27:53

Date of updated informed consent (dd MMM yyyy) 28 JAN 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) 28 JAN 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 _____

US3292245

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 28 JAN 2021 |
| Collection time (00:00-23:59) | 10:58 (24 HR) |
| Collection date and time (derived) | 28 JAN 2021 10:58 |

US3292245

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 28 JAN 2021 |
| Collection time (00:00 - 23:59) | 11:06 |
| Collection Date and Time (derived) | 28 JAN 2021 11:06 |

US3292245

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Apr 2021 15:49:02

Generated On: 09 Jun 2021 16:27:53

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 17:56:43

Generated On: 09 Jun 2021 16:27:53

| | |
|--|--|
| AEID | USA-US072-2021-MRNA-1273-P30 1000021 |
| Adverse event | PROSTATE CANCER |
| 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) | 01 NOV 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |

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US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 17:56:43

Generated On: 09 Jun 2021 16:27:53

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

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

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

Yes ☒

No ☐

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

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 14:19:33

Generated On: 09 Jun 2021 16:27:53

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 14:19:33

Generated On: 09 Jun 2021 16:27:53

| | | |
|--|--------------------------|----------------------------------|
| | 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 2000 | |
| 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) 16 Apr 2021 14:19:33

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Name of Medication GLUCOSAMINE

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 14:19:33

Generated On: 09 Jun 2021 16:27:53

| | | |
|--|--------------------------|----------------------------------|
| | 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 | 2000 |
| 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 (3)

Data signed: (b) (4) 16 Apr 2021 14:19:33

Generated On: 09 Jun 2021 16:27:53

Name of Medication COENZYME Q10

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 14:19:33

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2015 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 14:19:33

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Name of Medication CETYL MYRISTOLEATE

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 14:19:33

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 14:19:33

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Name of Medication KRILL OIL

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 14:19:33

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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 (6)

Data signed: (b) (4) 16 Apr 2021 14:19:33

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Name of Medication RESVERATROL

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 14:19:33

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 14:19:33

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Name of Medication DEHYDROEPIANDROSTERONE
(DHEA) SUPPLEMENT

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 14:19:33

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Name of Medication HAWTHORN BERRY

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 14:19:33

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 14:19:33

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Name of Medication ZINC

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 14:19:33

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 14:19:33

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Name of Medication LOSARTAN

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 (10)

Data signed: (b) (4) 16 Apr 2021 14:19:33

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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 type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN MAY 2016 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 14:19:33

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Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 3.125

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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US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 14:19:33

Generated On: 09 Jun 2021 16:27:53

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN MAY 2016 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 14:19:33

Generated On: 09 Jun 2021 16:27:53

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 14:19:33

Generated On: 09 Jun 2021 16:27:53

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN MAY 2016 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 14:19:33

Generated On: 09 Jun 2021 16:27:53

Name of Medication ACETYLSALICYLIC ACID (ASA)

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 14:19:33

Generated On: 09 Jun 2021 16:27:53

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK | 1990 |
| 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"/> |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 14:19:33

Generated On: 09 Jun 2021 16:27:53

Name of Medication PRASUGREL

Prophylaxis Yes ☒
No ☐

Indication CLOTTING PROPHYLAXIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

365 of 1967

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 14:19:33

Generated On: 09 Jun 2021 16:27:53

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

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 14:19:33

Generated On: 09 Jun 2021 16:27:53

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU PERVERTION

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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US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 14:19:33

Generated On: 09 Jun 2021 16:27:53

| | | |
|--|--------------------------|----------------------------------|
| | 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) | | 21 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) | | 21 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"/> |

US3292245

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Feb 2021 21:18:15

Generated On: 09 Jun 2021 16:27:53

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3292245

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:27:53

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

US3292245

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:27:53

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 ☐

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 17:56:43

Generated On: 09 Jun 2021 16:27:53

| | |
|--|--|
| SAEID | USA-US072-2021-MRNA-1273-P301000021 |
| 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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input 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) | 1 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 17:56:43

Generated On: 09 Jun 2021 16:27:53

| | |
|---|--|
| SAEID | USA-US072-2021-MRNA-1273-P301000021 |
| 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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input 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) | 1 |
| Date of submission (Pre-filled from custom function) | 29/APR/2021 09:36 |
| 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

US3292245 (Prod: Clinical Trials of Texas, Inc)

US3292245

Form: Participant Creation

Generated On: 09 Jun 2021 16:27:53

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Jan 2021 21:19:25 |
| User entered 'US3292245' | RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 16:04:45 |

US3292245

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:27:53

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 18:17:03 |

US3292245

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '20 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 16:04:46 |

US3292245

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 21 Aug 2020 18:17:03 |

US3292245

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:27:53

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered 'SCRN' | System | 21 Aug 2020 18:17:03 |

US3292245

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:53

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered (b) (6) 1952' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 16:04:47 |

US3292245

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:53

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '67' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:17:37 |

US3292245

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:53

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered 'YEARS' | System | 21 Aug 2020 18:17:37 |

US3292245

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:53

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered '67' | System | 20 Aug 2020 17:53:30 |

US3292245

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:53

[Sex](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Male (M)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:17:37 |

US3292245

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:53

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Hispanic or Latino (HISPANIC OR LATINO)' | (b) (4), (b) (6) | 21 Aug 2020 18:17:37 |

US3292245

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:53

White

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'l' | (b) (4), (b) (6) | 21 Aug 2020 18:17:37 |

US3292245

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:53

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:17:37 |

US3292245

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:53

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:17:37 |

US3292245

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:53

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:17:37 |

US3292245

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:53

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:17:37 |

US3292245

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:53

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:17:37 |

US3292245

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:53

If race is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:17:37 |

US3292245

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:53

[Unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:17:37 |

US3292245

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:53

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:17:37 |

US3292245

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:53

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '20 Aug 2020' | (b) (4) Nathan Cortez (b) (4) | 20 Aug 2020 17:53:30 |

US3292245

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered 'Aug 2020' | System | 20 Aug 2020 17:53:30 |

US3292245

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered '2020' | System | 20 Aug 2020 17:53:30 |

US3292245

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:53

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Amendment 2 (2)' | (b) (4) Nathan Cortez (b) (4) | 20 Aug 2020 17:53:30 |

US3292245

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) Nathan Cortez (b) (4) | 20 Aug 2020 17:53:30 |

US3292245

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:53

If No, indicate reason for screen fail

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4) Nathan Cortez (b) (4) | 20 Aug 2020 17:53:30 |

US3292245

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:53

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4) Nathan Cortez (b) (4) | 20 Aug 2020 17:53:30 |

US3292245

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:53

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4) Nathan Cortez (b) (4) | 20 Aug 2020 17:53:30 |

US3292245

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:53

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 16:04:46 |

US3292245

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:53

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered 'l' | System | 20 Aug 2020 17:53:37 |

US3292245

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) Nathan Cortez (b) (4) | 20 Aug 2020 17:53:37 |

US3292245

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:27:53

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 18:18:08 |

US3292245

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:53

[Condition](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| 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) | 22 Aug 2020 04:55:25 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 22 Aug 2020 04:55:25 |
| Data point term sent to Coder | System | 21 Aug 2020 18:19:36 |
| User entered 'Stent placement - x3' | (b) (4), (b) (6) | 21 Aug 2020 18:19:07 |

US3292245

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'UN May 2016' reason for change: | (b) (4) | |
| Data Entry Error | (b) (4), (b) (6) | 21 Aug 2020 18:20:04 |
| User entered 'un UNK 2016' | | 21 Aug 2020 18:19:07 |

US3292245

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:53

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:19:07 |

US3292245

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:53

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:19:07 |

US3292245

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'UN May 2016' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:20:04 |
| User entered 'un UNK 2016' | (b) (4), (b) (6) | 21 Aug 2020 18:19:07 |

US3292245

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:53

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:19:07 |

US3292245

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered 'May 2016' | System | 21 Aug 2020 18:20:04 |
| User entered 'Jan 2016' | System | 21 Aug 2020 18:19:07 |

US3292245

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:53

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered '2016' | System | 21 Aug 2020 18:19:07 |

US3292245

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered 'May 2016' | System | 21 Aug 2020 18:20:04 |
| User entered 'Jan 2016' | System | 21 Aug 2020 18:19:07 |

US3292245

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered '2016' | System | 21 Aug 2020 18:19:07 |

US3292245

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:53

[Condition](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| 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) | 22 Aug 2020 04:55:25 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 22 Aug 2020 04:55:25 |
| Data point term sent to Coder | System | 21 Aug 2020 18:20:37 |
| User entered 'stent placement - x1' | (b) (4), (b) (6) | 21 Aug 2020 18:19:43 |

US3292245

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '09 Jan 2018' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:19:43 |

US3292245

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:53

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:19:43 |

US3292245

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:53

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:19:43 |

US3292245

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '09 Jan 2018' | (b) (4), (b) (6) | 21 Aug 2020 18:19:43 |

US3292245

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:53

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:19:43 |

US3292245

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered 'Jan 2018' | System | 21 Aug 2020 18:19:43 |

US3292245

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:53

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered '2018' | System | 21 Aug 2020 18:19:43 |

US3292245

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered 'Jan 2018' | System | 21 Aug 2020 18:19:43 |

US3292245

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered '2018' | System | 21 Aug 2020 18:19:43 |

US3292245

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:53

[Condition](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0. | Coder Import (b) (4) | 21 Aug 2020 18:22:24 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 21 Aug 2020 18:22:24 |
| Data point term sent to Coder | System | 21 Aug 2020 18:21:38 |
| User entered 'Myocardial infarction' | (b) (4), (b) (6) | 21 Aug 2020 18:20:50 |

US3292245

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'un May 2016' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:20:50 |

US3292245

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:53

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:20:50 |

US3292245

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:53

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 18:20:50 |

US3292245

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'un May 2016' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:20:50 |

US3292245

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:53

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:20:50 |

US3292245

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered 'May 2016' | System | 21 Aug 2020 18:20:50 |

US3292245

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:53

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered '2016' | System | 21 Aug 2020 18:20:50 |

US3292245

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered 'May 2016' | System | 21 Aug 2020 18:20:50 |

US3292245

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered '2016' | System | 21 Aug 2020 18:20:50 |

US3292245

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:53

[Condition](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) (b) (4) | 21 Aug 2020 18:22:24 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 18:22:24 |
| Data point term sent to Coder System | (b) (4), (b) (6) | 21 Aug 2020 18:21:40 |
| User entered 'Myocardial infarction' | (b) (4), (b) (6) | 21 Aug 2020 18:21:18 |

US3292245

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '09 Jan 2018' | (b) (4), (b) (6) | 21 Aug 2020 18:21:18 |

US3292245

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:53

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:21:18 |

US3292245

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:53

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 18:21:18 |

US3292245

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '09 Jan 2018' | (b) (4), (b) (6) | 21 Aug 2020 18:21:18 |

US3292245

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:53

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:21:18 |

US3292245

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered 'Jan 2018' | System | 21 Aug 2020 18:21:18 |

US3292245

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:53

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered '2018' | System | 21 Aug 2020 18:21:18 |

US3292245

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered 'Jan 2018' | System | 21 Aug 2020 18:21:18 |

US3292245

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered '2018' | System | 21 Aug 2020 18:21:18 |

US3292245

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:53

[Condition](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) (b) (4) | 21 Aug 2020 18:23:25 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 18:23:25 |
| Data point term sent to Coder | System | 21 Aug 2020 18:22:44 |
| User entered 'Hyperlipidemia' | (b) (4), (b) (6) | 21 Aug 2020 18:21:54 |

US3292245

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'un UNK 2010' | (b) (4), (b) (6) | 21 Aug 2020 18:21:54 |

US3292245

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:53

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:21:54 |

US3292245

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:53

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 18:21:54 |

US3292245

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 18:21:54 |

US3292245

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:53

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:21:54 |

US3292245

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered 'Jan 2010' | System | 21 Aug 2020 18:21:54 |

US3292245

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered '2010' | System | 21 Aug 2020 18:21:54 |

US3292245

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered empty. | System | 21 Aug 2020 18:21:54 |

US3292245

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered empty. | System | 21 Aug 2020 18:21:54 |

US3292245

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:53

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 21 Aug 2020 18:25:24 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 21 Aug 2020 18:25:24 |
| Data point term sent to Coder | System | 21 Aug 2020 18:23:48 |
| User entered 'Chronic back pain' | (b) (4), (b) (6) | 21 Aug 2020 18:22:52 |

US3292245

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'un UNK 1990' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:22:52 |

US3292245

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:53

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:22:52 |

US3292245

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:53

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 18:22:52 |

US3292245

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 18:22:52 |

US3292245

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:53

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:22:52 |

US3292245

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered 'Jan 1990' | System | 21 Aug 2020 18:22:52 |

US3292245

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:53

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered '1990' | System | 21 Aug 2020 18:22:52 |

US3292245

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered empty. | System | 21 Aug 2020 18:22:52 |

US3292245

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered empty. | System | 21 Aug 2020 18:22:52 |

US3292245

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:53

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Pigmentation disorders, HLT: Hypopigmentation disorders, PT: Vitiligo, LLT: Vitiligo - version MedDRA\23.0. | (b) (4) Coder Import (b) (4) | 21 Aug 2020 18:25:24 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 21 Aug 2020 18:25:24 |
| Data point term sent to Coder | System | 21 Aug 2020 18:23:48 |
| User entered 'Vitiligo' | (b) (4), (b) (6) | 21 Aug 2020 18:23:26 |

US3292245

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'un UNK 2010' | (b) (4), (b) (6) | 21 Aug 2020 18:23:26 |

US3292245

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:53

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:23:26 |

US3292245

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:53

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 18:23:26 |

US3292245

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 18:23:26 |

US3292245

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:53

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:23:26 |

US3292245

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:53

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered 'Jan 2010' | System | 21 Aug 2020 18:23:26 |

US3292245

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:53

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered '2010' | System | 21 Aug 2020 18:23:26 |

US3292245

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered empty. | System | 21 Aug 2020 18:23:26 |

US3292245

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered empty. | System | 21 Aug 2020 18:23:26 |

US3292245

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:53

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 22 Sep 2020 00:33:51 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 22 Sep 2020 00:33:51 |
| Data point term sent to Coder | System | 22 Sep 2020 00:32:44 |
| User entered 'hypertension' | Dawn Killian (b) (4) | 22 Sep 2020 00:32:23 |
| | (b) (4) | |

US3292245

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'UN May 2016' | (b) (4) Dawn Killian (b) (4) | 22 Sep 2020 00:32:23 |

US3292245

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:53

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4) Dawn Killian (b) (4) | 22 Sep 2020 00:32:23 |

US3292245

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:53

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) Dawn Killian (b) (4) | 22 Sep 2020 00:32:23 |

US3292245

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4) Dawn Killian (b) (4) | 22 Sep 2020 00:32:23 |

US3292245

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:53

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4) Dawn Killian (b) (4) | 22 Sep 2020 00:32:23 |

US3292245

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered 'May 2016' | System | 22 Sep 2020 00:32:23 |

US3292245

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:53

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered '2016' | System | 22 Sep 2020 00:32:23 |

US3292245

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered empty. | System | 22 Sep 2020 00:32:23 |

US3292245

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered empty. | System | 22 Sep 2020 00:32:23 |

US3292245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 18:25:38 |

US3292245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '20 Aug 2020' | (b) (4), (b) (6) | 21 Aug 2020 18:25:38 |

US3292245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '11:21' | (b) (4), (b) (6) | 21 Aug 2020 18:25:38 |

US3292245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered '20 Aug 2020 11:21' | System | 21 Aug 2020 18:25:38 |

US3292245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[Height \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '175.0' cm | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:25:38 |
| DataPoint set to visible. | System | 20 Aug 2020 17:53:37 |

US3292245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[Weight \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '79.3' kg | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:25:38 |
| DataPoint set to visible. | System | 20 Aug 2020 17:53:37 |

US3292245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

BMI (xxx.x)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| Amendment Manager: User entered '25.89388' | System | 17 Sep 2020 00:16:11 |
| User entered '25.9' | System | 21 Aug 2020 18:25:38 |
| DataPoint set to visible. | System | 20 Aug 2020 17:53:37 |

US3292245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered 'kg/m2' | System | 21 Aug 2020 18:25:38 |
| DataPoint set to visible. | System | 20 Aug 2020 17:53:37 |

US3292245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User closed query 'Per CDM: per CCGs pages 15-16, 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM). | (b) (4), (b) (6) | 29 Sep 2020 14:22:20 |
| Query 'Per CDM: per CCGs pages 15-16, 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' answered with 'UPDATED' (Site from DM). | Victoria Hernandez (b) (4) | 22 Sep 2020 18:22:09 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 22 Sep 2020 18:22:02 |
| User opened query 'Per CDM: per CCGs pages 15-16, 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM). | (b) (4), (b) (6) | 26 Aug 2020 12:53:10 |
| User closed query 'Data is required. Please provide.' (Site from System). | | 24 Aug 2020 17:34:33 |
| Query 'Data is required. Please provide.' answered with 'ND' (Site from System). | | 21 Aug 2020 18:25:51 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 21 Aug 2020 18:25:38 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 18:25:38 |

US3292245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 18:25:38 |

US3292245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 18:25:38 |

US3292245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User closed query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM). | (b) (4) | 28 Oct 2020 10:51:42 |
| Query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' answered with 'UPDATED' (Site from DM). | (b) (4), (b) (6) | 07 Oct 2020 18:05:47 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | | 07 Oct 2020 18:05:29 |
| User opened query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM). | | 07 Oct 2020 12:52:54 |
| User closed query 'Data is required. Please provide.' (Site from System). | | 24 Aug 2020 17:34:36 |
| Query 'Data is required. Please provide.' answered with 'ND' (Site from System). | | 21 Aug 2020 18:25:56 |
| User opened query 'Data is required. Please provide.' System (Site from System). | | 21 Aug 2020 18:25:38 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 18:25:38 |

US3292245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered 'bpm' | System | 07 Oct 2020 18:05:29 |
| User entered empty. | System | 21 Aug 2020 18:25:38 |

US3292245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) (h) (4) | 22 Feb 2021 21:18:16 |
| User closed query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM). | (b) (4), (b) (6) | 28 Oct 2020 10:52:00 |
| Query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' answered with 'UPDATED' (Site from DM). | | 07 Oct 2020 18:05:51 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | | 07 Oct 2020 18:05:29 |
| User opened query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM). | | 07 Oct 2020 12:53:01 |
| User closed query 'Data is required. Please provide.' (Site from System). | | 24 Aug 2020 17:34:38 |
| Query 'Data is required. Please provide.' answered with 'ND' (Site from System). | | 21 Aug 2020 18:26:05 |
| User opened query 'Data is required. Please provide.' System | | 21 Aug 2020 18:25:38 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 18:25:38 |

US3292245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered 'breaths/min' | System | 07 Oct 2020 18:05:29 |
| User entered empty. | System | 21 Aug 2020 18:25:38 |

US3292245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User closed query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM). | (b) (4) | 28 Oct 2020 10:52:24 |
| Query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' answered with 'UPDATED' (Site from DM). | (b) (4), (b) (6) | 07 Oct 2020 18:05:55 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 07 Oct 2020 18:05:29 |
| User opened query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM). | (b) (4), (b) (6) | 07 Oct 2020 12:53:06 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 24 Aug 2020 17:34:40 |
| Query 'Data is required. Please provide.' answered with 'ND' (Site from System). | (b) (4), (b) (6) | 21 Aug 2020 18:26:07 |
| User opened query 'Data is required. Please provide.' System | (b) (4), (b) (6) | 21 Aug 2020 18:25:38 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 18:25:38 |

US3292245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered 'mmHg' | System | 07 Oct 2020 18:05:29 |
| User entered empty. | System | 21 Aug 2020 18:25:38 |

US3292245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User closed query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM). | (b) (4) | 28 Oct 2020 10:52:46 |
| Query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' answered with 'UPDATED' (Site from DM). | (b) (4), (b) (6) | 07 Oct 2020 18:05:59 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 07 Oct 2020 18:05:29 |
| User opened query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM). | (b) (4), (b) (6) | 07 Oct 2020 12:53:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 24 Aug 2020 17:34:43 |
| Query 'Data is required. Please provide.' answered with 'ND' (Site from System). | (b) (4), (b) (6) | 21 Aug 2020 18:26:08 |
| User opened query 'Data is required. Please provide.' System | (b) (4), (b) (6) | 21 Aug 2020 18:25:38 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 18:25:38 |

US3292245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered 'mmHg' | System | 07 Oct 2020 18:05:29 |
| User entered empty. | System | 21 Aug 2020 18:25:38 |

US3292245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |

US3292245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |

US3292245

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:53

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:27:50 |

US3292245

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:53

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '20 Aug 2020' | (b) (4), (b) (6) | 21 Aug 2020 18:27:50 |

US3292245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:53

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:28:34 |

US3292245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:53

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:28:34 |

US3292245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:53

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 18:28:34 |

US3292245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:53

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 18:28:34 |

US3292245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:53

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 18:28:34 |

US3292245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:53

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 18:28:34 |

US3292245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:53

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 18:28:34 |

US3292245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:53

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 18:28:34 |

US3292245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:53

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:28:34 |

US3292245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:53

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 18:28:34 |

US3292245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:53

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 18:28:34 |

US3292245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:53

Other

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 18:28:34 |

US3292245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:53

[Specify](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Real estate agent' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:28:34 |

US3292245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:53

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:28:34 |

US3292245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:53

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:28:34 |

US3292245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:53

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:28:34 |

US3292245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:53

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:28:34 |

US3292245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:53

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:28:34 |

US3292245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:53

[Resides in a single family home \(i.e., detached housing\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'I' | (b) (4), (b) (6) | 21 Aug 2020 18:28:34 |

US3292245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:53

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 18:28:34 |

US3292245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:53

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 18:28:34 |

US3292245

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:27:53

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:28:47 |

US3292245

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:27:53

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '20 Aug 2020' | (b) (4), (b) (6) | 21 Aug 2020 18:28:47 |

US3292245

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 21 Aug 2020 18:28:47 |

US3292245

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:27:53

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'VISIT1' | System | 21 Aug 2020 18:28:47 |

US3292245

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '20 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 17:39:19 |

US3292245

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:53

[What was the participant's randomization number?](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4) System | 21 Aug 2020 05:53:42 |
| Amendment Manager: Data point set to conformant. | System | 21 Aug 2020 05:53:42 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 20 Aug 2020 17:39:19 |
| User entered '187344' (non-conformant). | RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 17:39:19 |

US3292245

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:53

[In what Cohort was the participant enrolled?](#)

| Audit | User | Time (GMT) |
|-------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '>=65 years (3)' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 17:39:19 |

US3292245

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:53

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 18:29:47 |

US3292245

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:53

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 18:29:47 |

US3292245

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:53

Severe obesity (body mass index > or = 40kg/m2

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:29:47 |

US3292245

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:53

Diabetes (Type I, Type 2, or gestational)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 18:29:47 |

US3292245

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:53

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:29:47 |

US3292245

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:53

[Human Immunodeficiency Virus \(HIV\) infection](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| Amendment Manager: DataPoint set to visible. | System | 19 Sep 2020 10:37:01 |
| Amendment Manager inserted this DataPoint. | System | 19 Sep 2020 01:45:42 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:53

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:31:03 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:53

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:31:03 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:53

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:31:03 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:53

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:31:03 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User accepted default value 'Pre-Dose (PREDOSE)' | | 21 Aug 2020 18:31:03 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:31:03 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '20 Aug 2020' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:31:03 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '11:17' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:31:03 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered '20 Aug 2020 11:17' | System | 21 Aug 2020 18:31:03 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '36.7' C | (b) (4), (b) (6) | 21 Aug 2020 18:31:03 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:31:03 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:31:03 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '67' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:31:03 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'bpm' | System | 21 Aug 2020 18:31:03 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '20' | (b) (4), (b) (6) | 21 Aug 2020 18:31:03 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'breaths/min' | System | 21 Aug 2020 18:31:03 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '120' | (b) (4), (b) (6) | 21 Aug 2020 18:31:03 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'mmHg' | System | 21 Aug 2020 18:31:03 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '82' | (b) (4), (b) (6) | 21 Aug 2020 18:31:03 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'mmHg' | System | 21 Aug 2020 18:31:03 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:53

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:31:03 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:53

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:31:03 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User accepted default value 'Post-Dose (POSTDOSE)' | | 21 Aug 2020 18:32:04 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:32:04 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '20 Aug 2020' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:32:04 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '13:16' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:32:04 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered '20 Aug 2020 13:16' | System | 21 Aug 2020 18:32:04 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '36.2' C | (b) (4), (b) (6) | 21 Aug 2020 18:32:04 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:32:04 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 18:32:04 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '57' | (b) (4), (b) (6) | 21 Aug 2020 18:32:04 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'bpm' | System | 21 Aug 2020 18:32:04 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '16' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:32:04 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'breaths/min' | System | 21 Aug 2020 18:32:04 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '115' | (b) (4), (b) (6) | 21 Aug 2020 18:32:04 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'mmHg' | System | 21 Aug 2020 18:32:04 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '77' | (b) (4), (b) (6) | 21 Aug 2020 18:32:04 |

US3292245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'mmHg' | System | 21 Aug 2020 18:32:04 |

US3292245

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:53

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:32:13 |

US3292245

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:53

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 18:32:13 |

US3292245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:53

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) Nathan Cortez (b) (4) | 20 Aug 2020 17:54:17 |

US3292245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:53

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4) Nathan Cortez (b) (4) | 20 Aug 2020 17:54:17 |

US3292245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4) Nathan Cortez (b) (4) | 20 Aug 2020 17:54:17 |

US3292245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:53

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:53

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '20 Aug 2020' | (b) (4) Nathan Cortez (b) (4) | 20 Aug 2020 17:54:17 |

US3292245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:53

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '12:46' | (b) (4) Nathan Cortez (b) (4) | 20 Aug 2020 17:54:17 |

US3292245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:53

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered '20 Aug 2020 12:46' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:53

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4) Nathan Cortez (b) (4) | 20 Aug 2020 17:54:17 |

US3292245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:53

What was the frequency of the study treatment dosing?

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'ONCE' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:53

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'INTRAMUSCULAR' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:53

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 18:32:34 |

US3292245

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:53

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '20 Aug 2020' | (b) (4), (b) (6) | 21 Aug 2020 18:32:34 |

US3292245

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:53

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '11:55' | (b) (4), (b) (6) | 21 Aug 2020 18:32:34 |

US3292245

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:53

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered '20 Aug 2020 11:55' | System | 21 Aug 2020 18:32:34 |

US3292245

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:27:53

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '20 Aug 2020' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:32:54 |

US3292245

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:27:53

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | (b) (4), (b) (6) | 21 Aug 2020 18:32:54 |

US3292245

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:27:53

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:32:54 |

US3292245

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:27:53

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '11:45' | (b) (4), (b) (6) | 21 Aug 2020 18:32:54 |

US3292245

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:27:53

Collection date and time (derived)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered '20 Aug 2020 11:45' | System | 21 Aug 2020 18:32:54 |

US3292245

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:27:53

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | | 1 Aug 2020 18:33:01 |

US3292245

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:27:53

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 18:33:01 |

US3292245

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:27:53

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 18:33:01 |

US3292245

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:27:53

Collection date and time (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered empty. | System | 21 Aug 2020 18:33:01 |

US3292245

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 18:33:08 |

US3292245

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'I' | System | 21 Aug 2020 18:33:08 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T13:20:17', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'faf447f1-2621-4f27-bc47-333f00fba658' | System | 20 Aug 2020 18:24:12 |
| User entered 'Yes (Y)' | System | 20 Aug 2020 18:24:12 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T13:20:24', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'faf447f1-2621-4f27-bc47-333f00fba658' | System | 20 Aug 2020 18:24:12 |
| User entered '97.2' | System | 20 Aug 2020 18:24:12 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T13:20:32', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'faf447f1-2621-4f27-bc47-333f00fba658' | System | 20 Aug 2020 18:24:12 |
| User entered 'No (N)' | System | 20 Aug 2020 18:24:12 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T13:20:38', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'faf447f1-2621-4f27-bc47-333f00fba658' | System | 20 Aug 2020 18:24:12 |
| User entered '20 Aug 2020 13:20' | System | 20 Aug 2020 18:24:12 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '20 Aug 2020 13:06' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '20 Aug 2020 15:36' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 1, after vaccination (at home)' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T20:10:52', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '2e9071a1-45a2-40c1-bd74-7a6c86b6349c' | System | 21 Aug 2020 01:18:48 |
| User entered 'Yes (Y)' | System | 21 Aug 2020 01:18:48 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T20:14:58', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '2e9071a1-45a2-40c1-bd74-7a6c86b6349c' | System | 21 Aug 2020 01:18:48 |
| User entered '99.0' | System | 21 Aug 2020 01:18:48 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T20:15:04', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '2e9071a1-45a2-40c1-bd74-7a6c86b6349c' | System | 21 Aug 2020 01:18:48 |
| User entered 'No (N)' | System | 21 Aug 2020 01:18:48 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T20:15:13', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '2e9071a1-45a2-40c1-bd74-7a6c86b6349c' | System | 21 Aug 2020 01:18:48 |
| User entered '20 Aug 2020 20:15' | System | 21 Aug 2020 01:18:48 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '20 Aug 2020 16:31' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '21 Aug 2020 11:59' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 2' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:53

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-21T21:04:06', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'fdb16f5f-f5e7-4dab-9f22-03020097bea9' | System | 22 Aug 2020 02:09:03 |
| User entered 'Yes (Y)' | System | 22 Aug 2020 02:09:03 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:53

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-21T21:05:08', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'fdb16f5f-f5e7-4dab-9f22-03020097bea9' | System | 22 Aug 2020 02:09:03 |
| User entered '98.5' | System | 22 Aug 2020 02:09:03 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-21T21:05:15', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'fdb16f5f-f5e7-4dab-9f22-03020097bea9' | System | 22 Aug 2020 02:09:03 |
| User entered 'No (N)' | System | 22 Aug 2020 02:09:03 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-21T21:05:24', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'fdb16f5f-f5e7-4dab-9f22-03020097bea9' | System | 22 Aug 2020 02:09:03 |
| User entered '21 Aug 2020 21:05' | System | 22 Aug 2020 02:09:03 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '21 Aug 2020 12:00' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '22 Aug 2020 11:59' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 3' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:53

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-22T21:11:35', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '2852b2bb-15c9-4a3d-9dd3-55c8f041c5b7' | System | 23 Aug 2020 02:15:33 |
| User entered 'Yes (Y)' | System | 23 Aug 2020 02:15:33 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:53

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-22T21:11:41', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '2852b2bb-15c9-4a3d-9dd3-55c8f041c5b7' | System | 23 Aug 2020 02:15:33 |
| User entered '98.1' | System | 23 Aug 2020 02:15:33 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-22T21:11:46', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '2852b2bb-15c9-4a3d-9dd3-55c8f041c5b7' | System | 23 Aug 2020 02:15:33 |
| User entered 'No (N)' | System | 23 Aug 2020 02:15:33 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-22T21:11:54', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '2852b2bb-15c9-4a3d-9dd3-55c8f041c5b7' | System | 23 Aug 2020 02:15:33 |
| User entered '22 Aug 2020 21:11' | System | 23 Aug 2020 02:15:33 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '22 Aug 2020 12:00' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '23 Aug 2020 11:59' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 4' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:53

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-23T23:30:04', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'ea1fb341-ed06-4453-94c5-1b72e1c66794' | System | 24 Aug 2020 04:34:40 |
| User entered 'Yes (Y)' | System | 24 Aug 2020 04:34:40 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:53

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-23T23:30:52', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'ea1fb341-ed06-4453-94c5-1b72e1c66794' User entered '98.5' | System | 24 Aug 2020 04:34:40 |
| | System | 24 Aug 2020 04:34:40 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-23T23:30:57', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'ea1fb341-ed06-4453-94c5-1b72e1c66794' | System | 24 Aug 2020 04:34:40 |
| User entered 'No (N)' | System | 24 Aug 2020 04:34:40 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-23T23:31:01', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'ea1fb341-ed06-4453-94c5-1b72e1c66794' | System | 24 Aug 2020 04:34:40 |
| User entered '23 Aug 2020 23:31' | System | 24 Aug 2020 04:34:40 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '23 Aug 2020 12:00' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '24 Aug 2020 11:59' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 5' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:53

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-24T20:01:47', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '1de73ad4-0de8-46cd-a9dd-971100c42409' | System | 25 Aug 2020 01:05:39 |
| User entered 'Yes (Y)' | System | 25 Aug 2020 01:05:39 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:53

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-24T20:01:53', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '1de73ad4-0de8-46cd-a9dd-971100c42409' User entered '98.1' | System | 25 Aug 2020 01:05:39 |
| | System | 25 Aug 2020 01:05:39 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-24T20:01:56', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '1de73ad4-0de8-46cd-a9dd-971100c42409' | System | 25 Aug 2020 01:05:39 |
| User entered 'No (N)' | System | 25 Aug 2020 01:05:39 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-24T20:01:59', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '1de73ad4-0de8-46cd-a9dd-971100c42409' | System | 25 Aug 2020 01:05:39 |
| User entered '24 Aug 2020 20:01' | System | 25 Aug 2020 01:05:39 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '24 Aug 2020 12:00' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '25 Aug 2020 11:59' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 6' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:53

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T00:00:22', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'f359897f-e9be-4c07-9c07-d316eb06a1ea' | System | 26 Aug 2020 05:05:40 |
| User entered 'Yes (Y)' | System | 26 Aug 2020 05:05:40 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:53

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T00:01:51', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'f359897f-e9be-4c07-9c07-d316eb06a1ea' User entered '98.1' | System | 26 Aug 2020 05:05:40 |
| | System | 26 Aug 2020 05:05:40 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T00:01:56', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'f359897f-e9be-4c07-9c07-d316eb06a1ea' | System | 26 Aug 2020 05:05:40 |
| User entered 'No (N)' | System | 26 Aug 2020 05:05:40 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T00:02:01', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'f359897f-e9be-4c07-9c07-d316eb06a1ea' | System | 26 Aug 2020 05:05:40 |
| User entered '26 Aug 2020 00:02' | System | 26 Aug 2020 05:05:40 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '25 Aug 2020 12:00' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '26 Aug 2020 11:59' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 7' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:53

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T21:35:17', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '04c6111a-a9ad-4235-8680-bc12429215c4' | System | 27 Aug 2020 02:39:10 |
| User entered 'Yes (Y)' | System | 27 Aug 2020 02:39:10 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:53

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T21:35:23', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '04c6111a-a9ad-4235-8680-bc12429215c4' | System | 27 Aug 2020 02:39:10 |
| User entered '98.3' | System | 27 Aug 2020 02:39:10 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T21:35:28', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '04c6111a-a9ad-4235-8680-bc12429215c4' | System | 27 Aug 2020 02:39:10 |
| User entered 'No (N)' | System | 27 Aug 2020 02:39:10 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T21:35:31', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '04c6111a-a9ad-4235-8680-bc12429215c4' | System | 27 Aug 2020 02:39:10 |
| User entered '26 Aug 2020 21:35' | System | 27 Aug 2020 02:39:10 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '26 Aug 2020 12:00' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '27 Aug 2020 11:59' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T13:20:56', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '4ec0f6b8-5642-47ac-a3ed-8e351fba869f' | System | 20 Aug 2020 18:24:49 |
| User entered 'None (1)' | System | 20 Aug 2020 18:24:49 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T13:21:00', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '4ec0f6b8-5642-47ac-a3ed-8e351fba869f' | System | 20 Aug 2020 18:24:49 |
| User entered 'No (N)' | System | 20 Aug 2020 18:24:49 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T13:21:03', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '4ec0f6b8-5642-47ac-a3ed-8e351fba869f' | System | 20 Aug 2020 18:24:49 |
| User entered 'No (N)' | System | 20 Aug 2020 18:24:49 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T13:21:10', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '4ec0f6b8-5642-47ac-a3ed-8e351fba869f' | System | 20 Aug 2020 18:24:49 |
| User entered 'None (1)' | System | 20 Aug 2020 18:24:49 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T13:21:15', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '4ec0f6b8-5642-47ac-a3ed-8e351fba869f' | System | 20 Aug 2020 18:24:49 |
| User entered '20 Aug 2020 13:21' | System | 20 Aug 2020 18:24:49 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '20 Aug 2020 13:06' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '20 Aug 2020 15:36' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 1, after vaccination (at home)' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T20:15:33', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '252d4a59-7b86-42f3-8b67-2f80421162e6' | System | 21 Aug 2020 01:20:05 |
| User entered 'Does not interfere with activity (2)' | System | 21 Aug 2020 01:20:05 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T20:16:00', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '252d4a59-7b86-42f3-8b67-2f80421162e6' | System | 21 Aug 2020 01:20:05 |
| User entered 'No (N)' | System | 21 Aug 2020 01:20:05 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T20:16:17', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '252d4a59-7b86-42f3-8b67-2f80421162e6' | System | 21 Aug 2020 01:20:05 |
| User entered 'No (N)' | System | 21 Aug 2020 01:20:05 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T20:16:25', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '252d4a59-7b86-42f3-8b67-2f80421162e6' | System | 21 Aug 2020 01:20:05 |
| User entered 'None (1)' | System | 21 Aug 2020 01:20:05 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T20:16:30', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '252d4a59-7b86-42f3-8b67-2f80421162e6' | System | 21 Aug 2020 01:20:05 |
| User entered '20 Aug 2020 20:16' | System | 21 Aug 2020 01:20:05 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '20 Aug 2020 16:31' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '21 Aug 2020 11:59' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 2' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-21T21:05:35', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '8d0b1660-7dd1-4fd1-ac34-303aab3ba66e' | System | 22 Aug 2020 02:09:48 |
| User entered 'Does not interfere with activity (2)' | System | 22 Aug 2020 02:09:48 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:53

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-21T21:05:48', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '8d0b1660-7dd1-4fd1-ac34-303aab3ba66e' | System | 22 Aug 2020 02:09:48 |
| User entered 'No (N)' | System | 22 Aug 2020 02:09:48 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-21T21:05:51', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '8d0b1660-7dd1-4fd1-ac34-303aab3ba66e' | System | 22 Aug 2020 02:09:48 |
| User entered 'No (N)' | System | 22 Aug 2020 02:09:48 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-21T21:06:02', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '8d0b1660-7dd1-4fd1-ac34-303aab3ba66e' | System | 22 Aug 2020 02:09:48 |
| User entered 'None (1)' | System | 22 Aug 2020 02:09:48 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-21T21:06:06', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '8d0b1660-7dd1-4fd1-ac34-303aab3ba66e' | System | 22 Aug 2020 02:09:48 |
| User entered '21 Aug 2020 21:06' | System | 22 Aug 2020 02:09:48 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '21 Aug 2020 12:00' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '22 Aug 2020 11:59' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 3' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-22T21:12:05', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'a74529dd-2ce5-48e3-a79a-e26e53a33646' | System | 23 Aug 2020 02:16:03 |
| User entered 'Does not interfere with activity (2)' | System | 23 Aug 2020 02:16:03 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:53

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-22T21:12:08', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'a74529dd-2ce5-48e3-a79a-e26e53a33646' | System | 23 Aug 2020 02:16:03 |
| User entered 'No (N)' | System | 23 Aug 2020 02:16:03 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-22T21:12:12', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'a74529dd-2ce5-48e3-a79a-e26e53a33646' | System | 23 Aug 2020 02:16:03 |
| User entered 'No (N)' | System | 23 Aug 2020 02:16:03 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-22T21:12:20', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'a74529dd-2ce5-48e3-a79a-e26e53a33646' | System | 23 Aug 2020 02:16:03 |
| User entered 'None (1)' | System | 23 Aug 2020 02:16:03 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-22T21:12:24', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'a74529dd-2ce5-48e3-a79a-e26e53a33646' | System | 23 Aug 2020 02:16:03 |
| User entered '22 Aug 2020 21:12' | System | 23 Aug 2020 02:16:03 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '22 Aug 2020 12:00' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '23 Aug 2020 11:59' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 4' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-23T21:52:28', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '93a74659-27f0-460a-b298-7b77a82235dd' | System | 24 Aug 2020 02:56:28 |
| User entered 'None (1)' | System | 24 Aug 2020 02:56:28 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:53

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-23T21:52:33', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '93a74659-27f0-460a-b298-7b77a82235dd' | System | 24 Aug 2020 02:56:28 |
| User entered 'No (N)' | System | 24 Aug 2020 02:56:28 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-23T21:52:37', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '93a74659-27f0-460a-b298-7b77a82235dd' | System | 24 Aug 2020 02:56:28 |
| User entered 'No (N)' | System | 24 Aug 2020 02:56:28 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-23T21:52:45', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '93a74659-27f0-460a-b298-7b77a82235dd' | System | 24 Aug 2020 02:56:28 |
| User entered 'None (1)' | System | 24 Aug 2020 02:56:28 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-23T21:52:48', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '93a74659-27f0-460a-b298-7b77a82235dd' | System | 24 Aug 2020 02:56:28 |
| User entered '23 Aug 2020 21:52' | System | 24 Aug 2020 02:56:28 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '23 Aug 2020 12:00' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '24 Aug 2020 11:59' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 5' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-24T20:02:08', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '49c564b9-1368-482d-b723-549d2375efa7' | System | 25 Aug 2020 01:06:01 |
| User entered 'None (1)' | System | 25 Aug 2020 01:06:01 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:53

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-24T20:02:11', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '49c564b9-1368-482d-b723-549d2375efa7' | System | 25 Aug 2020 01:06:01 |
| User entered 'No (N)' | System | 25 Aug 2020 01:06:01 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-24T20:02:14', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '49c564b9-1368-482d-b723-549d2375efa7' | System | 25 Aug 2020 01:06:01 |
| User entered 'No (N)' | System | 25 Aug 2020 01:06:01 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-24T20:02:20', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '49c564b9-1368-482d-b723-549d2375efa7' | System | 25 Aug 2020 01:06:01 |
| User entered 'None (1)' | System | 25 Aug 2020 01:06:01 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-24T20:02:22', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '49c564b9-1368-482d-b723-549d2375efa7' | System | 25 Aug 2020 01:06:01 |
| User entered '24 Aug 2020 20:02' | System | 25 Aug 2020 01:06:01 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '24 Aug 2020 12:00' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '25 Aug 2020 11:59' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 6' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T00:02:09', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '0c3389d8-f85d-4dfe-835f-1462bd7703fd' | System | 26 Aug 2020 05:05:58 |
| User entered 'None (1)' | System | 26 Aug 2020 05:05:58 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:53

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T00:02:11', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '0c3389d8-f85d-4dfe-835f-1462bd7703fd' | System | 26 Aug 2020 05:05:58 |
| User entered 'No (N)' | System | 26 Aug 2020 05:05:58 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T00:02:14', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '0c3389d8-f85d-4dfe-835f-1462bd7703fd' | System | 26 Aug 2020 05:05:58 |
| User entered 'No (N)' | System | 26 Aug 2020 05:05:58 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T00:02:18', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '0c3389d8-f85d-4dfe-835f-1462bd7703fd' | System | 26 Aug 2020 05:05:58 |
| User entered 'None (1)' | System | 26 Aug 2020 05:05:58 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T00:02:21', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '0c3389d8-f85d-4dfe-835f-1462bd7703fd' | System | 26 Aug 2020 05:05:58 |
| User entered '26 Aug 2020 00:02' | System | 26 Aug 2020 05:05:58 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '25 Aug 2020 12:00' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '26 Aug 2020 11:59' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 7' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T21:35:40', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '12dd84b9-78e2-4382-a6cc-cb16e1405bac' | System | 27 Aug 2020 02:39:36 |
| User entered 'None (1)' | System | 27 Aug 2020 02:39:36 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:53

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T21:35:43', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '12dd84b9-78e2-4382-a6cc-cb16e1405bac' | System | 27 Aug 2020 02:39:36 |
| User entered 'No (N)' | System | 27 Aug 2020 02:39:36 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T21:35:46', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '12dd84b9-78e2-4382-a6cc-cb16e1405bac' | System | 27 Aug 2020 02:39:36 |
| User entered 'No (N)' | System | 27 Aug 2020 02:39:36 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T21:35:50', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '12dd84b9-78e2-4382-a6cc-cb16e1405bac' | System | 27 Aug 2020 02:39:36 |
| User entered 'None (1)' | System | 27 Aug 2020 02:39:36 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T21:35:56', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '12dd84b9-78e2-4382-a6cc-cb16e1405bac' | System | 27 Aug 2020 02:39:36 |
| User entered '26 Aug 2020 21:35' | System | 27 Aug 2020 02:39:36 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '26 Aug 2020 12:00' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '27 Aug 2020 11:59' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T13:21:21', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'c8bd3ea0-8e31-4d04-9d5e-61ae1ac4d9f5' | System | 20 Aug 2020 18:25:28 |
| User entered 'None (0)' | System | 20 Aug 2020 18:25:28 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T13:21:24', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'c8bd3ea0-8e31-4d04-9d5e-61ae1ac4d9f5' | System | 20 Aug 2020 18:25:28 |
| User entered 'None (0)' | System | 20 Aug 2020 18:25:28 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T13:21:28', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'c8bd3ea0-8e31-4d04-9d5e-61ae1ac4d9f5' | System | 20 Aug 2020 18:25:28 |
| User entered 'None (0)' | System | 20 Aug 2020 18:25:28 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T13:21:33', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'c8bd3ea0-8e31-4d04-9d5e-61ae1ac4d9f5' | System | 20 Aug 2020 18:25:28 |
| User entered 'None (0)' | System | 20 Aug 2020 18:25:28 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T13:21:37', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'c8bd3ea0-8e31-4d04-9d5e-61ae1ac4d9f5' | System | 20 Aug 2020 18:25:28 |
| User entered 'None (0)' | System | 20 Aug 2020 18:25:28 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T13:21:40', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'c8bd3ea0-8e31-4d04-9d5e-61ae1ac4d9f5' | System | 20 Aug 2020 18:25:28 |
| User entered 'None (0)' | System | 20 Aug 2020 18:25:28 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T13:21:47', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'c8bd3ea0-8e31-4d04-9d5e-61ae1ac4d9f5' | System | 20 Aug 2020 18:25:28 |
| User entered 'No (N)' | System | 20 Aug 2020 18:25:28 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T13:21:51', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'c8bd3ea0-8e31-4d04-9d5e-61ae1ac4d9f5' | System | 20 Aug 2020 18:25:28 |
| User entered '20 Aug 2020 13:21' | System | 20 Aug 2020 18:25:28 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '20 Aug 2020 13:06' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '20 Aug 2020 15:36' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 1, after vaccination (at home)' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T20:16:35', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '7b2efcc9-d3bf-4d8b-bb4d-8dbf5959032a' | System | 21 Aug 2020 01:20:47 |
| User entered 'None (0)' | System | 21 Aug 2020 01:20:47 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T20:16:42', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '7b2efcc9-d3bf-4d8b-bb4d-8dbf5959032a' | System | 21 Aug 2020 01:20:47 |
| User entered 'None (0)' | System | 21 Aug 2020 01:20:47 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T20:16:46', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '7b2efcc9-d3bf-4d8b-bb4d-8dbf5959032a' | System | 21 Aug 2020 01:20:47 |
| User entered 'None (0)' | System | 21 Aug 2020 01:20:47 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T20:16:49', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '7b2efcc9-d3bf-4d8b-bb4d-8dbf5959032a' | System | 21 Aug 2020 01:20:47 |
| User entered 'None (0)' | System | 21 Aug 2020 01:20:47 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T20:16:53', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '7b2efcc9-d3bf-4d8b-bb4d-8dbf5959032a' | System | 21 Aug 2020 01:20:47 |
| User entered 'None (0)' | System | 21 Aug 2020 01:20:47 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T20:16:56', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '7b2efcc9-d3bf-4d8b-bb4d-8dbf5959032a' | System | 21 Aug 2020 01:20:47 |
| User entered 'None (0)' | System | 21 Aug 2020 01:20:47 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T20:17:04', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '7b2efcc9-d3bf-4d8b-bb4d-8dbf5959032a' | System | 21 Aug 2020 01:20:47 |
| User entered 'No (N)' | System | 21 Aug 2020 01:20:47 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-20T20:17:07', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '7b2efcc9-d3bf-4d8b-bb4d-8dbf5959032a' | System | 21 Aug 2020 01:20:47 |
| User entered '20 Aug 2020 20:17' | System | 21 Aug 2020 01:20:47 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '20 Aug 2020 16:31' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '21 Aug 2020 11:59' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 2' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-21T21:06:10', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '7cd67245-9b8a-4f24-b640-aab523a55690' | System | 22 Aug 2020 02:10:18 |
| User entered 'None (0)' | System | 22 Aug 2020 02:10:18 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-21T21:06:13', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '7cd67245-9b8a-4f24-b640-aab523a55690' | System | 22 Aug 2020 02:10:18 |
| User entered 'None (0)' | System | 22 Aug 2020 02:10:18 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-21T21:06:19', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '7cd67245-9b8a-4f24-b640-aab523a55690' | System | 22 Aug 2020 02:10:18 |
| User entered 'None (0)' | System | 22 Aug 2020 02:10:18 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-21T21:06:25', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '7cd67245-9b8a-4f24-b640-aab523a55690' | System | 22 Aug 2020 02:10:18 |
| User entered 'None (0)' | System | 22 Aug 2020 02:10:18 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-21T21:06:27', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '7cd67245-9b8a-4f24-b640-aab523a55690' | System | 22 Aug 2020 02:10:18 |
| User entered 'None (0)' | System | 22 Aug 2020 02:10:18 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-21T21:06:30', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '7cd67245-9b8a-4f24-b640-aab523a55690' | System | 22 Aug 2020 02:10:18 |
| User entered 'None (0)' | System | 22 Aug 2020 02:10:18 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-21T21:06:35', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '7cd67245-9b8a-4f24-b640-aab523a55690' | System | 22 Aug 2020 02:10:18 |
| User entered 'No (N)' | System | 22 Aug 2020 02:10:18 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-21T21:06:38', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '7cd67245-9b8a-4f24-b640-aab523a55690' | System | 22 Aug 2020 02:10:18 |
| User entered '21 Aug 2020 21:06' | System | 22 Aug 2020 02:10:18 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '21 Aug 2020 12:00' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '22 Aug 2020 11:59' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 3' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-22T21:12:29', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '3b53e301-fa61-4d6c-a02e-74b1b5ac3e96' | System | 23 Aug 2020 02:16:37 |
| User entered 'None (0)' | System | 23 Aug 2020 02:16:37 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-22T21:12:34', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '3b53e301-fa61-4d6c-a02e-74b1b5ac3e96' | System | 23 Aug 2020 02:16:37 |
| User entered 'None (0)' | System | 23 Aug 2020 02:16:37 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-22T21:12:39', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '3b53e301-fa61-4d6c-a02e-74b1b5ac3e96' | System | 23 Aug 2020 02:16:37 |
| User entered 'None (0)' | System | 23 Aug 2020 02:16:37 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-22T21:12:41', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '3b53e301-fa61-4d6c-a02e-74b1b5ac3e96' | System | 23 Aug 2020 02:16:37 |
| User entered 'None (0)' | System | 23 Aug 2020 02:16:37 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-22T21:12:44', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '3b53e301-fa61-4d6c-a02e-74b1b5ac3e96' | System | 23 Aug 2020 02:16:37 |
| User entered 'None (0)' | System | 23 Aug 2020 02:16:37 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-22T21:12:47', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '3b53e301-fa61-4d6c-a02e-74b1b5ac3e96' | System | 23 Aug 2020 02:16:37 |
| User entered 'None (0)' | System | 23 Aug 2020 02:16:37 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-22T21:12:56', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '3b53e301-fa61-4d6c-a02e-74b1b5ac3e96' | System | 23 Aug 2020 02:16:37 |
| User entered 'No (N)' | System | 23 Aug 2020 02:16:37 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-22T21:12:59', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '3b53e301-fa61-4d6c-a02e-74b1b5ac3e96' | System | 23 Aug 2020 02:16:37 |
| User entered '22 Aug 2020 21:12' | System | 23 Aug 2020 02:16:37 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '22 Aug 2020 12:00' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '23 Aug 2020 11:59' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 4' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-23T21:52:54', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '29be6996-7d27-4f56-912b-511d3704bda6' | System | 24 Aug 2020 02:57:59 |
| User entered 'None (0)' | System | 24 Aug 2020 02:57:59 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-23T21:53:14', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '29be6996-7d27-4f56-912b-511d3704bda6' | System | 24 Aug 2020 02:57:59 |
| User entered 'None (0)' | System | 24 Aug 2020 02:57:59 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-23T21:53:22', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '29be6996-7d27-4f56-912b-511d3704bda6' | System | 24 Aug 2020 02:57:59 |
| User entered 'None (0)' | System | 24 Aug 2020 02:57:59 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-23T21:53:26', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '29be6996-7d27-4f56-912b-511d3704bda6' | System | 24 Aug 2020 02:57:59 |
| User entered 'None (0)' | System | 24 Aug 2020 02:57:59 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-23T21:53:43', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '29be6996-7d27-4f56-912b-511d3704bda6' | System | 24 Aug 2020 02:57:59 |
| User entered 'None (0)' | System | 24 Aug 2020 02:57:59 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-23T21:53:47', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '29be6996-7d27-4f56-912b-511d3704bda6' | System | 24 Aug 2020 02:57:59 |
| User entered 'None (0)' | System | 24 Aug 2020 02:57:59 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-23T21:53:56', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '29be6996-7d27-4f56-912b-511d3704bda6' | System | 24 Aug 2020 02:57:59 |
| User entered 'No (N)' | System | 24 Aug 2020 02:57:59 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-23T21:54:21', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '29be6996-7d27-4f56-912b-511d3704bda6' | System | 24 Aug 2020 02:57:59 |
| User entered '23 Aug 2020 21:54' | System | 24 Aug 2020 02:57:59 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '23 Aug 2020 12:00' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '24 Aug 2020 11:59' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 5' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-24T20:02:30', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '4b215921-0875-4cba-bbb3-673eb09e4483' | System | 25 Aug 2020 01:06:35 |
| User entered 'None (0)' | System | 25 Aug 2020 01:06:35 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-24T20:02:37', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '4b215921-0875-4cba-bbb3-673eb09e4483' | System | 25 Aug 2020 01:06:35 |
| User entered 'None (0)' | System | 25 Aug 2020 01:06:35 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-24T20:02:41', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '4b215921-0875-4cba-bbb3-673eb09e4483' | System | 25 Aug 2020 01:06:35 |
| User entered 'None (0)' | System | 25 Aug 2020 01:06:35 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-24T20:02:44', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '4b215921-0875-4cba-bbb3-673eb09e4483' | System | 25 Aug 2020 01:06:35 |
| User entered 'None (0)' | System | 25 Aug 2020 01:06:35 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-24T20:02:46', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '4b215921-0875-4cba-bbb3-673eb09e4483' | System | 25 Aug 2020 01:06:35 |
| User entered 'None (0)' | System | 25 Aug 2020 01:06:35 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-24T20:02:49', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '4b215921-0875-4cba-bbb3-673eb09e4483' | System | 25 Aug 2020 01:06:35 |
| User entered 'None (0)' | System | 25 Aug 2020 01:06:35 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-24T20:02:53', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '4b215921-0875-4cba-bbb3-673eb09e4483' | System | 25 Aug 2020 01:06:35 |
| User entered 'No (N)' | System | 25 Aug 2020 01:06:35 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-24T20:02:56', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '4b215921-0875-4cba-bbb3-673eb09e4483' | System | 25 Aug 2020 01:06:35 |
| User entered '24 Aug 2020 20:02' | System | 25 Aug 2020 01:06:35 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '24 Aug 2020 12:00' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '25 Aug 2020 11:59' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 6' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T00:02:25', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '8d6b31db-2a48-49e4-8fee-cf4fae20bed3' | System | 26 Aug 2020 05:06:26 |
| User entered 'None (0)' | System | 26 Aug 2020 05:06:26 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T00:02:28', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '8d6b31db-2a48-49e4-8fee-cf4fae20bed3' | System | 26 Aug 2020 05:06:26 |
| User entered 'None (0)' | System | 26 Aug 2020 05:06:26 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T00:02:31', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '8d6b31db-2a48-49e4-8fee-cf4fae20bed3' | System | 26 Aug 2020 05:06:26 |
| User entered 'None (0)' | System | 26 Aug 2020 05:06:26 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T00:02:34', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '8d6b31db-2a48-49e4-8fee-cf4fae20bed3' | System | 26 Aug 2020 05:06:26 |
| User entered 'None (0)' | System | 26 Aug 2020 05:06:26 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T00:02:36', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '8d6b31db-2a48-49e4-8fee-cf4fae20bed3' | System | 26 Aug 2020 05:06:26 |
| User entered 'None (0)' | System | 26 Aug 2020 05:06:26 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T00:02:38', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '8d6b31db-2a48-49e4-8fee-cf4fae20bed3' | System | 26 Aug 2020 05:06:26 |
| User entered 'None (0)' | System | 26 Aug 2020 05:06:26 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T00:02:43', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '8d6b31db-2a48-49e4-8fee-cf4fae20bed3' | System | 26 Aug 2020 05:06:26 |
| User entered 'No (N)' | System | 26 Aug 2020 05:06:26 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T00:02:46', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '8d6b31db-2a48-49e4-8fee-cf4fae20bed3' | System | 26 Aug 2020 05:06:26 |
| User entered '26 Aug 2020 00:02' | System | 26 Aug 2020 05:06:26 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '25 Aug 2020 12:00' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '26 Aug 2020 11:59' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 7' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

HEADACHE

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T21:36:01', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'cd1fec9-aed4-497b-a0d7-48279346ba28' | System | 27 Aug 2020 02:40:04 |
| User entered 'None (0)' | System | 27 Aug 2020 02:40:04 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

FATIGUE

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T21:36:04', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'cd1fec9-aed4-497b-a0d7-48279346ba28' | System | 27 Aug 2020 02:40:04 |
| User entered 'None (0)' | System | 27 Aug 2020 02:40:04 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T21:36:07', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'cd1fec9-aed4-497b-a0d7-48279346ba28' | System | 27 Aug 2020 02:40:04 |
| User entered 'None (0)' | System | 27 Aug 2020 02:40:04 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T21:36:09', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'cd1fec9-aed4-497b-a0d7-48279346ba28' | System | 27 Aug 2020 02:40:04 |
| User entered 'None (0)' | System | 27 Aug 2020 02:40:04 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T21:36:11', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'cd1fec9-aed4-497b-a0d7-48279346ba28' | System | 27 Aug 2020 02:40:04 |
| User entered 'None (0)' | System | 27 Aug 2020 02:40:04 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

CHILLS

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T21:36:14', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'cd1fec9-aed4-497b-a0d7-48279346ba28' | System | 27 Aug 2020 02:40:04 |
| User entered 'None (0)' | System | 27 Aug 2020 02:40:04 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T21:36:21', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'cd1fec9-aed4-497b-a0d7-48279346ba28' | System | 27 Aug 2020 02:40:04 |
| User entered 'No (N)' | System | 27 Aug 2020 02:40:04 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-08-26T21:36:24', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'cd1fec9-aed4-497b-a0d7-48279346ba28' | System | 27 Aug 2020 02:40:04 |
| User entered '26 Aug 2020 21:36' | System | 27 Aug 2020 02:40:04 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '26 Aug 2020 12:00' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '27 Aug 2020 11:59' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) Kristy Trevino (b) (4) | 28 Aug 2020 21:35:57 |

US3292245

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '28 Aug 2020' | (b) (4) Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 21:35:57 |

US3292245

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Kristy Trevino (b) (4) | 28 Aug 2020 21:35:57 |

US3292245

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4) Kristy Trevino (b) (4) (b) (4) | 28 Aug 2020 21:35:57 |

US3292245

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) Kristy Trevino (b) (4) | 28 Aug 2020 21:36:02 |

US3292245

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User entered 'l' | System | 28 Aug 2020 21:36:02 |

US3292245

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) Kristy Trevino (b) (4) | 07 Sep 2020 18:40:06 |

US3292245

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | (b) (4), (b) (6) | 10 Sep 2020 15:33:37 |
| Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'date is correct ' (Site from System). | Kristy Trevino (b) (4) | 07 Sep 2020 18:41:00 |
| User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 07 Sep 2020 18:40:06 |
| User entered '7 Sep 2020' | Kristy Trevino (b) (4) | 07 Sep 2020 18:40:06 |

US3292245

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Kristy Trevino (b) (4) | 07 Sep 2020 18:40:06 |

US3292245

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4) Kristy Trevino (b) (4) | 07 Sep 2020 18:40:06 |

US3292245

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) Kristy Trevino (b) (4) | 07 Sep 2020 18:41:13 |

US3292245

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User entered 'l' | System | 07 Sep 2020 18:41:13 |

US3292245

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) Antonio Gutierrez (b) (4) | 11 Sep 2020 22:36:30 |

US3292245

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '11 Sep 2020' | (b) (4) Antonio Gutierrez (b) (4) | 11 Sep 2020 22:36:30 |

US3292245

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Antonio Gutierrez (b) (4) | 11 Sep 2020 22:36:30 |

US3292245

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4) Antonio Gutierrez (b) (4) | 11 Sep 2020 22:36:30 |

US3292245

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) Antonio Gutierrez (b) (4) | 11 Sep 2020 22:36:56 |

US3292245

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User entered 'l' | System | 11 Sep 2020 22:36:56 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:53

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered 'Yes (Y)' | (b) (4) Gerardo Pena (b) (4) | 17 Sep 2020 16:56:54 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:53

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '17 Sep 2020' | (b) (4) Gerardo Pena (b) (4) | 17 Sep 2020 16:56:54 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered 'Clinic (Clinic)' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 16:56:54 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:53

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'VISIT2' | System | 17 Sep 2020 16:56:54 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 16:57:43 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered 'Yes (Y)' | (b) (4) Gerardo Pena (b) (4) | 17 Sep 2020 16:57:43 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '17 Sep 2020' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 16:57:43 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '09:44' | (b) (4) Gerardo Pena (b) (4) | 17 Sep 2020 16:57:43 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered '17 Sep 2020 09:44' | System | 17 Sep 2020 16:57:43 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '36.6' C | (b) (4) Gerardo Pena (b) (4) | 17 Sep 2020 16:57:43 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered 'Oral (Oral)' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 16:57:43 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered empty. | (b) (4) Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 16:57:43 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '70' | (b) (4) Gerardo Pena (b) (4) | 17 Sep 2020 16:57:43 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'bpm' | System | 17 Sep 2020 16:57:43 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '12' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 16:57:43 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'breaths/min' | System | 17 Sep 2020 16:57:43 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '120' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 16:57:43 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'mmHg' | System | 17 Sep 2020 16:57:43 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '74' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 16:57:43 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:53

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'mmHg' | System | 17 Sep 2020 16:57:43 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 16:58:15 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered 'Yes (Y)' | (b) (4) Gerardo Pena (b) (4) | 17 Sep 2020 16:58:15 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '17 Sep 2020' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 16:58:15 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '11:30' | (b) (4) Gerardo Pena (b) (4) | 17 Sep 2020 16:58:15 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered '17 Sep 2020 11:30' | System | 17 Sep 2020 16:58:15 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '36.4' C | (b) (4) Gerardo Pena (b) (4) | 17 Sep 2020 16:58:15 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered 'Oral (Oral)' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 16:58:15 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered empty. | (b) (4) Gerardo Pena (b) (4) | 17 Sep 2020 16:58:15 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '64' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 16:58:15 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'bpm' | System | 17 Sep 2020 16:58:15 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '12' | (b) (4) Gerardo Pena (b) (4) | 17 Sep 2020 16:58:15 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'breaths/min' | System | 17 Sep 2020 16:58:15 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '111' | (b) (4) Gerardo Pena (b) (4) | 17 Sep 2020 16:58:15 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'mmHg' | System | 17 Sep 2020 16:58:15 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '73' | (b) (4) Gerardo Pena (b) (4) | 17 Sep 2020 16:58:15 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:53

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'mmHg' | System | 17 Sep 2020 16:58:15 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:53

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered 'Yes (Y)' | (b) (4) Gerardo Pena (b) (4) | 17 Sep 2020 16:58:28 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:53

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '17 Sep 2020' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 16:58:28 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:53

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 17 Sep 2020 16:09:36 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:53

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4), (b) (6) | 17 Sep 2020 16:09:36 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4), (b) (6) | 17 Sep 2020 16:09:36 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:53

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:53

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '17 Sep 2020' | (b) (4), (b) (6) | 17 Sep 2020 16:09:36 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:53

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '11:00' | (b) (4), (b) (6) | 17 Sep 2020 16:09:36 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:53

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered '17 Sep 2020 11:00' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:53

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4), (b) (6) | 17 Sep 2020 16:09:36 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:53

What was the frequency of the study treatment dosing?

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'ONCE' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:53

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'INTRAMUSCULAR' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:53

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered 'Yes (Y)' | (b) (4) Gerardo Pena (b) (4) | 17 Sep 2020 16:58:59 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:53

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '17 Sep 2020' | (b) (4) Gerardo Pena (b) (4) | 17 Sep 2020 16:58:59 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:53

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '10:00' | (b) (4) Gerardo Pena (b) (4) | 17 Sep 2020 16:58:59 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:53

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered '17 Sep 2020 10:00' | System | 17 Sep 2020 16:58:59 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:27:53

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '17 Sep 2020' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 16:59:17 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:27:53

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 16:59:17 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:27:53

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) Gerardo Pena (b) (4) | 17 Sep 2020 16:59:17 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:27:53

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '10:04' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 16:59:17 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:27:53

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered '17 Sep 2020 10:04' | System | 17 Sep 2020 16:59:17 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:27:53

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 16:59:17 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:27:53

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4) Gerardo Pena (b) (4) | 17 Sep 2020 16:59:17 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:27:53

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4) Gerardo Pena (b) (4) | 17 Sep 2020 16:59:17 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:27:53

Collection date and time (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered empty. | System | 17 Sep 2020 16:59:17 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) Gerardo Pena (b) (4) | 17 Sep 2020 16:59:46 |

US3292245

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'l' | System | 17 Sep 2020 16:59:46 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 17 Sep 2020 16:09:36 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T11:28:54', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '2736b583-b404-41db-8c6b-1c6cdebbde24' | System | 17 Sep 2020 16:33:11 |
| User entered 'Yes (Y)' | System | 17 Sep 2020 16:33:11 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T11:29:05', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '2736b583-b404-41db-8c6b-1c6cdebbde24' | System | 17 Sep 2020 16:33:11 |
| User entered '97.5' | System | 17 Sep 2020 16:33:11 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T11:29:12', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '2736b583-b404-41db-8c6b-1c6cdebbde24' | System | 17 Sep 2020 16:33:11 |
| User entered 'No (N)' | System | 17 Sep 2020 16:33:11 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T11:29:19', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '2736b583-b404-41db-8c6b-1c6cdebbde24' | System | 17 Sep 2020 16:33:11 |
| User entered '17 Sep 2020 11:29' | System | 17 Sep 2020 16:33:11 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '17 Sep 2020 11:20' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '17 Sep 2020 13:50' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 17 Sep 2020 16:09:36 |
| User entered 'Day 1, after vaccination (at home)' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T20:50:09', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'd604c10a-2099-4f5f-a36e-b192cf3a394c' | System | 18 Sep 2020 01:55:43 |
| User entered 'Yes (Y)' | System | 18 Sep 2020 01:55:43 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T20:51:36', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'd604c10a-2099-4f5f-a36e-b192cf3a394c' | System | 18 Sep 2020 01:55:43 |
| User entered '98.5' | System | 18 Sep 2020 01:55:43 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T20:51:43', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'd604c10a-2099-4f5f-a36e-b192cf3a394c' | System | 18 Sep 2020 01:55:43 |
| User entered 'No (N)' | System | 18 Sep 2020 01:55:43 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T20:51:49', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'd604c10a-2099-4f5f-a36e-b192cf3a394c' | System | 18 Sep 2020 01:55:43 |
| User entered '17 Sep 2020 20:51' | System | 18 Sep 2020 01:55:43 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '17 Sep 2020 14:45' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '18 Sep 2020 11:59' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 17 Sep 2020 16:09:36 |
| User entered 'Day 2' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:53

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-18T20:14:51', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '0ec98f6f-92c2-412c-aa20-304a8f10c396' | System | 19 Sep 2020 01:19:12 |
| User entered 'Yes (Y)' | System | 19 Sep 2020 01:19:12 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:53

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-18T20:14:59', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '0ec98f6f-92c2-412c-aa20-304a8f10c396' | System | 19 Sep 2020 01:19:12 |
| User entered '100.3' | System | 19 Sep 2020 01:19:12 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-18T20:15:05', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '0ec98f6f-92c2-412c-aa20-304a8f10c396' | System | 19 Sep 2020 01:19:12 |
| User entered 'Yes (Y)' | System | 19 Sep 2020 01:19:12 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject will be contacted on D36 safety call where information will be gathered. ' (Site from System). | | 10 Nov 2020 11:02:04 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | System | 19 Sep 2020 01:19:12 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-18T20:15:17', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '0ec98f6f-92c2-412c-aa20-304a8f10c396' | System | 19 Sep 2020 01:19:12 |
| User entered '1' | System | 19 Sep 2020 01:19:12 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:53

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-18T20:15:17', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '0ec98f6f-92c2-412c-aa20-304a8f10c396' | System | 19 Sep 2020 01:19:12 |
| User entered '0' | System | 19 Sep 2020 01:19:12 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-18T20:15:21', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '0ec98f6f-92c2-412c-aa20-304a8f10c396' | System | 19 Sep 2020 01:19:12 |
| User entered '18 Sep 2020 20:15' | System | 19 Sep 2020 01:19:12 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '18 Sep 2020 12:00' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '19 Sep 2020 11:59' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 17 Sep 2020 16:09:36 |
| User entered 'Day 3' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:53

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T00:02:27', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'dbc16ff1-4581-4be0-a8a7-a5af9083b7b4' | System | 20 Sep 2020 05:06:29 |
| User entered 'Yes (Y)' | System | 20 Sep 2020 05:06:29 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:53

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T00:02:33', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'dbc16ff1-4581-4be0-a8a7-a5af9083b7b4' | System | 20 Sep 2020 05:06:29 |
| User entered '98.0' | System | 20 Sep 2020 05:06:29 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T00:02:36', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'dbc16ff1-4581-4be0-a8a7-a5af9083b7b4' | System | 20 Sep 2020 05:06:29 |
| User entered 'No (N)' | System | 20 Sep 2020 05:06:29 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T00:02:39', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'dbc16ff1-4581-4be0-a8a7-a5af9083b7b4' | System | 20 Sep 2020 05:06:29 |
| User entered '20 Sep 2020 00:02' | System | 20 Sep 2020 05:06:29 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '19 Sep 2020 12:00' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '20 Sep 2020 11:59' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 17 Sep 2020 16:09:36 |
| User entered 'Day 4' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:53

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T23:21:58', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '0b4f7d46-4eac-4ecf-9017-ce956fa78323' | System | 21 Sep 2020 04:26:23 |
| User entered 'Yes (Y)' | System | 21 Sep 2020 04:26:23 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:53

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T23:22:26', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '0b4f7d46-4eac-4ecf-9017-ce956fa78323' | System | 21 Sep 2020 04:26:23 |
| User entered '97.7' | System | 21 Sep 2020 04:26:23 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T23:22:30', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '0b4f7d46-4eac-4ecf-9017-ce956fa78323' | System | 21 Sep 2020 04:26:23 |
| User entered 'No (N)' | System | 21 Sep 2020 04:26:23 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T23:22:33', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '0b4f7d46-4eac-4ecf-9017-ce956fa78323' | System | 21 Sep 2020 04:26:23 |
| User entered '20 Sep 2020 23:22' | System | 21 Sep 2020 04:26:23 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '20 Sep 2020 12:00' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '21 Sep 2020 11:59' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 17 Sep 2020 16:09:36 |
| User entered 'Day 5' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:53

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-21T23:45:38', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '85abf17e-9530-470e-83dd-00eb5c620d80' | System | 22 Sep 2020 04:49:42 |
| User entered 'Yes (Y)' | System | 22 Sep 2020 04:49:42 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:53

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-21T23:45:44', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '85abf17e-9530-470e-83dd-00eb5c620d80' | System | 22 Sep 2020 04:49:42 |
| User entered '98.1' | System | 22 Sep 2020 04:49:42 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-21T23:45:49', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '85abf17e-9530-470e-83dd-00eb5c620d80' | System | 22 Sep 2020 04:49:42 |
| User entered 'No (N)' | System | 22 Sep 2020 04:49:42 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-21T23:45:52', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '85abf17e-9530-470e-83dd-00eb5c620d80' | System | 22 Sep 2020 04:49:42 |
| User entered '21 Sep 2020 23:45' | System | 22 Sep 2020 04:49:42 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '21 Sep 2020 12:00' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '22 Sep 2020 11:59' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 17 Sep 2020 16:09:36 |
| User entered 'Day 6' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:53

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-22T20:13:34', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '60c92104-d84e-41b2-93bf-925e52e25ebe' | System | 23 Sep 2020 01:18:51 |
| User entered 'Yes (Y)' | System | 23 Sep 2020 01:18:51 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:53

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-22T20:14:54', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '60c92104-d84e-41b2-93bf-925e52e25ebe' User entered '98.1' | System | 23 Sep 2020 01:18:51 |
| | System | 23 Sep 2020 01:18:51 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-22T20:14:59', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '60c92104-d84e-41b2-93bf-925e52e25ebe' | System | 23 Sep 2020 01:18:51 |
| User entered 'No (N)' | System | 23 Sep 2020 01:18:51 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-22T20:15:02', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '60c92104-d84e-41b2-93bf-925e52e25ebe' | System | 23 Sep 2020 01:18:51 |
| User entered '22 Sep 2020 20:15' | System | 23 Sep 2020 01:18:51 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '22 Sep 2020 12:00' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '23 Sep 2020 11:59' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 17 Sep 2020 16:09:36 |
| User entered 'Day 7' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:53

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-23T23:36:30', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '05fc1c38-035b-4904-8bd4-b1585d98b51d' | System | 24 Sep 2020 04:41:50 |
| User entered 'Yes (Y)' | System | 24 Sep 2020 04:41:50 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:53

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-23T23:37:52', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '05fc1c38-035b-4904-8bd4-b1585d98b51d' User entered '98.5' | System | 24 Sep 2020 04:41:50 |
| | System | 24 Sep 2020 04:41:50 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-23T23:37:58', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '05fc1c38-035b-4904-8bd4-b1585d98b51d' | System | 24 Sep 2020 04:41:50 |
| User entered 'No (N)' | System | 24 Sep 2020 04:41:50 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-23T23:38:01', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '05fc1c38-035b-4904-8bd4-b1585d98b51d' | System | 24 Sep 2020 04:41:50 |
| User entered '23 Sep 2020 23:38' | System | 24 Sep 2020 04:41:50 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '23 Sep 2020 12:00' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '24 Sep 2020 11:59' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 17 Sep 2020 16:09:36 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T11:29:26', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'f15ea3c2-5c78-4e04-a88a-49d60d632887' | System | 17 Sep 2020 16:33:37 |
| User entered 'None (1)' | System | 17 Sep 2020 16:33:37 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T11:29:32', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'f15ea3c2-5c78-4e04-a88a-49d60d632887' | System | 17 Sep 2020 16:33:37 |
| User entered 'No (N)' | System | 17 Sep 2020 16:33:37 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T11:29:37', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'f15ea3c2-5c78-4e04-a88a-49d60d632887' | System | 17 Sep 2020 16:33:37 |
| User entered 'No (N)' | System | 17 Sep 2020 16:33:37 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T11:29:43', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'f15ea3c2-5c78-4e04-a88a-49d60d632887' | System | 17 Sep 2020 16:33:37 |
| User entered 'None (1)' | System | 17 Sep 2020 16:33:37 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T11:29:47', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'f15ea3c2-5c78-4e04-a88a-49d60d632887' | System | 17 Sep 2020 16:33:37 |
| User entered '17 Sep 2020 11:29' | System | 17 Sep 2020 16:33:37 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '17 Sep 2020 11:20' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '17 Sep 2020 13:50' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 17 Sep 2020 16:09:36 |
| User entered 'Day 1, after vaccination (at home)' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T20:52:06', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '5a7305c4-c813-4f84-aa3d-9a1cb6c0f46b' | System | 18 Sep 2020 01:56:37 |
| User entered 'None (1)' | System | 18 Sep 2020 01:56:37 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T20:52:25', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '5a7305c4-c813-4f84-aa3d-9a1cb6c0f46b' | System | 18 Sep 2020 01:56:37 |
| User entered 'No (N)' | System | 18 Sep 2020 01:56:37 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T20:52:31', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '5a7305c4-c813-4f84-aa3d-9a1cb6c0f46b' | System | 18 Sep 2020 01:56:37 |
| User entered 'No (N)' | System | 18 Sep 2020 01:56:37 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T20:52:42', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '5a7305c4-c813-4f84-aa3d-9a1cb6c0f46b' | System | 18 Sep 2020 01:56:37 |
| User entered 'None (1)' | System | 18 Sep 2020 01:56:37 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T20:52:46', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '5a7305c4-c813-4f84-aa3d-9a1cb6c0f46b' | System | 18 Sep 2020 01:56:37 |
| User entered '17 Sep 2020 20:52' | System | 18 Sep 2020 01:56:37 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '17 Sep 2020 14:45' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '18 Sep 2020 11:59' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 17 Sep 2020 16:09:36 |
| User entered 'Day 2' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-18T20:15:35', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '440287a4-1679-4ae9-a7b6-6f34f70c6343' | System | 19 Sep 2020 01:20:04 |
| User entered 'Does not interfere with activity (2)' | System | 19 Sep 2020 01:20:04 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:53

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-18T20:15:46', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '440287a4-1679-4ae9-a7b6-6f34f70c6343' | System | 19 Sep 2020 01:20:04 |
| User entered 'No (N)' | System | 19 Sep 2020 01:20:04 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-18T20:15:50', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '440287a4-1679-4ae9-a7b6-6f34f70c6343' | System | 19 Sep 2020 01:20:04 |
| User entered 'No (N)' | System | 19 Sep 2020 01:20:04 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-18T20:16:07', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '440287a4-1679-4ae9-a7b6-6f34f70c6343' | System | 19 Sep 2020 01:20:04 |
| User entered 'None (1)' | System | 19 Sep 2020 01:20:04 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-18T20:16:12', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '440287a4-1679-4ae9-a7b6-6f34f70c6343' | System | 19 Sep 2020 01:20:04 |
| User entered '18 Sep 2020 20:16' | System | 19 Sep 2020 01:20:04 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '18 Sep 2020 12:00' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '19 Sep 2020 11:59' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 17 Sep 2020 16:09:36 |
| User entered 'Day 3' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T00:02:51', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '57433520-5fb8-463b-8f5a-18a3c74f9896' | System | 20 Sep 2020 05:06:55 |
| User entered 'Does not interfere with activity (2)' | System | 20 Sep 2020 05:06:55 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:53

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T00:02:54', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '57433520-5fb8-463b-8f5a-18a3c74f9896' | System | 20 Sep 2020 05:06:55 |
| User entered 'No (N)' | System | 20 Sep 2020 05:06:55 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T00:02:57', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '57433520-5fb8-463b-8f5a-18a3c74f9896' | System | 20 Sep 2020 05:06:55 |
| User entered 'No (N)' | System | 20 Sep 2020 05:06:55 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T00:03:01', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '57433520-5fb8-463b-8f5a-18a3c74f9896' | System | 20 Sep 2020 05:06:55 |
| User entered 'None (1)' | System | 20 Sep 2020 05:06:55 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T00:03:04', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '57433520-5fb8-463b-8f5a-18a3c74f9896' | System | 20 Sep 2020 05:06:55 |
| User entered '20 Sep 2020 00:03' | System | 20 Sep 2020 05:06:55 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '19 Sep 2020 12:00' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '20 Sep 2020 11:59' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 17 Sep 2020 16:09:36 |
| User entered 'Day 4' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T23:22:39', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '6809a4ac-9d79-4213-a9da-9d20bfe5f3ea' | System | 21 Sep 2020 04:26:46 |
| User entered 'None (1)' | System | 21 Sep 2020 04:26:46 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:53

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T23:22:45', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '6809a4ac-9d79-4213-a9da-9d20bfe5f3ea' | System | 21 Sep 2020 04:26:46 |
| User entered 'No (N)' | System | 21 Sep 2020 04:26:46 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T23:22:48', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '6809a4ac-9d79-4213-a9da-9d20bfe5f3ea' | System | 21 Sep 2020 04:26:46 |
| User entered 'No (N)' | System | 21 Sep 2020 04:26:46 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T23:22:51', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '6809a4ac-9d79-4213-a9da-9d20bfe5f3ea' | System | 21 Sep 2020 04:26:46 |
| User entered 'None (1)' | System | 21 Sep 2020 04:26:46 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T23:22:54', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '6809a4ac-9d79-4213-a9da-9d20bfe5f3ea' | System | 21 Sep 2020 04:26:46 |
| User entered '20 Sep 2020 23:22' | System | 21 Sep 2020 04:26:46 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '20 Sep 2020 12:00' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '21 Sep 2020 11:59' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 17 Sep 2020 16:09:36 |
| User entered 'Day 5' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-21T23:45:58', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '1d93f8e9-b19b-43b5-b1ac-0d206b80f917' | System | 22 Sep 2020 04:49:58 |
| User entered 'None (1)' | System | 22 Sep 2020 04:49:58 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:53

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-21T23:46:01', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '1d93f8e9-b19b-43b5-b1ac-0d206b80f917' | System | 22 Sep 2020 04:49:58 |
| User entered 'No (N)' | System | 22 Sep 2020 04:49:58 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-21T23:46:03', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '1d93f8e9-b19b-43b5-b1ac-0d206b80f917' | System | 22 Sep 2020 04:49:58 |
| User entered 'No (N)' | System | 22 Sep 2020 04:49:58 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-21T23:46:06', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '1d93f8e9-b19b-43b5-b1ac-0d206b80f917' | System | 22 Sep 2020 04:49:58 |
| User entered 'None (1)' | System | 22 Sep 2020 04:49:58 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-21T23:46:08', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '1d93f8e9-b19b-43b5-b1ac-0d206b80f917' | System | 22 Sep 2020 04:49:58 |
| User entered '21 Sep 2020 23:46' | System | 22 Sep 2020 04:49:58 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '21 Sep 2020 12:00' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '22 Sep 2020 11:59' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 17 Sep 2020 16:09:36 |
| User entered 'Day 6' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-22T20:15:08', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '177df9e2-c4bd-4735-830e-e2e18e1b6399' | System | 23 Sep 2020 01:19:16 |
| User entered 'None (1)' | System | 23 Sep 2020 01:19:16 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:53

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-22T20:15:13', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '177df9e2-c4bd-4735-830e-e2e18e1b6399' | System | 23 Sep 2020 01:19:16 |
| User entered 'No (N)' | System | 23 Sep 2020 01:19:16 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-22T20:15:17', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '177df9e2-c4bd-4735-830e-e2e18e1b6399' | System | 23 Sep 2020 01:19:16 |
| User entered 'No (N)' | System | 23 Sep 2020 01:19:16 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-22T20:15:23', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '177df9e2-c4bd-4735-830e-e2e18e1b6399' | System | 23 Sep 2020 01:19:16 |
| User entered 'None (1)' | System | 23 Sep 2020 01:19:16 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-22T20:15:26', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '177df9e2-c4bd-4735-830e-e2e18e1b6399' | System | 23 Sep 2020 01:19:16 |
| User entered '22 Sep 2020 20:15' | System | 23 Sep 2020 01:19:16 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '22 Sep 2020 12:00' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '23 Sep 2020 11:59' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 17 Sep 2020 16:09:36 |
| User entered 'Day 7' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-23T23:38:06', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '131ecbd9-de6c-4338-be8f-d7c03e014b4f' | System | 24 Sep 2020 04:42:07 |
| User entered 'None (1)' | System | 24 Sep 2020 04:42:07 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:53

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-23T23:38:09', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '131ecbd9-de6c-4338-be8f-d7c03e014b4f' | System | 24 Sep 2020 04:42:07 |
| User entered 'No (N)' | System | 24 Sep 2020 04:42:07 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-23T23:38:11', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '131ecbd9-de6c-4338-be8f-d7c03e014b4f' | System | 24 Sep 2020 04:42:07 |
| User entered 'No (N)' | System | 24 Sep 2020 04:42:07 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:53

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-23T23:38:14', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '131ecbd9-de6c-4338-be8f-d7c03e014b4f' | System | 24 Sep 2020 04:42:07 |
| User entered 'None (1)' | System | 24 Sep 2020 04:42:07 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:53

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-23T23:38:17', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '131ecbd9-de6c-4338-be8f-d7c03e014b4f' | System | 24 Sep 2020 04:42:07 |
| User entered '23 Sep 2020 23:38' | System | 24 Sep 2020 04:42:07 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '23 Sep 2020 12:00' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '24 Sep 2020 11:59' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 17 Sep 2020 16:09:36 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T11:29:51', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '52981300-b4d0-48dd-ac67-68ec5b4f10b8' | System | 17 Sep 2020 16:34:13 |
| User entered 'None (0)' | System | 17 Sep 2020 16:34:13 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T11:29:54', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '52981300-b4d0-48dd-ac67-68ec5b4f10b8' | System | 17 Sep 2020 16:34:13 |
| User entered 'None (0)' | System | 17 Sep 2020 16:34:13 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T11:29:57', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '52981300-b4d0-48dd-ac67-68ec5b4f10b8' | System | 17 Sep 2020 16:34:13 |
| User entered 'None (0)' | System | 17 Sep 2020 16:34:13 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T11:30:00', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '52981300-b4d0-48dd-ac67-68ec5b4f10b8' | System | 17 Sep 2020 16:34:13 |
| User entered 'None (0)' | System | 17 Sep 2020 16:34:13 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T11:30:05', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '52981300-b4d0-48dd-ac67-68ec5b4f10b8' | System | 17 Sep 2020 16:34:13 |
| User entered 'None (0)' | System | 17 Sep 2020 16:34:13 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T11:30:12', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '52981300-b4d0-48dd-ac67-68ec5b4f10b8' | System | 17 Sep 2020 16:34:13 |
| User entered 'None (0)' | System | 17 Sep 2020 16:34:13 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T11:30:18', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '52981300-b4d0-48dd-ac67-68ec5b4f10b8' | System | 17 Sep 2020 16:34:13 |
| User entered 'No (N)' | System | 17 Sep 2020 16:34:13 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T11:30:21', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '52981300-b4d0-48dd-ac67-68ec5b4f10b8' | System | 17 Sep 2020 16:34:13 |
| User entered '17 Sep 2020 11:30' | System | 17 Sep 2020 16:34:13 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '17 Sep 2020 11:20' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '17 Sep 2020 13:50' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 17 Sep 2020 16:09:36 |
| User entered 'Day 1, after vaccination (at home)' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T20:52:50', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '5d1c234f-f829-41ac-ab21-74f957d05d52' | System | 18 Sep 2020 01:57:10 |
| User entered 'None (0)' | System | 18 Sep 2020 01:57:10 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T20:52:53', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '5d1c234f-f829-41ac-ab21-74f957d05d52' | System | 18 Sep 2020 01:57:10 |
| User entered 'None (0)' | System | 18 Sep 2020 01:57:10 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T20:52:55', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '5d1c234f-f829-41ac-ab21-74f957d05d52' | System | 18 Sep 2020 01:57:10 |
| User entered 'None (0)' | System | 18 Sep 2020 01:57:10 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T20:53:00', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '5d1c234f-f829-41ac-ab21-74f957d05d52' | System | 18 Sep 2020 01:57:10 |
| User entered 'None (0)' | System | 18 Sep 2020 01:57:10 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T20:53:02', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '5d1c234f-f829-41ac-ab21-74f957d05d52' | System | 18 Sep 2020 01:57:10 |
| User entered 'None (0)' | System | 18 Sep 2020 01:57:10 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T20:53:07', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '5d1c234f-f829-41ac-ab21-74f957d05d52' | System | 18 Sep 2020 01:57:10 |
| User entered 'None (0)' | System | 18 Sep 2020 01:57:10 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T20:53:15', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '5d1c234f-f829-41ac-ab21-74f957d05d52' | System | 18 Sep 2020 01:57:10 |
| User entered 'No (N)' | System | 18 Sep 2020 01:57:10 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-17T20:53:17', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '5d1c234f-f829-41ac-ab21-74f957d05d52' | System | 18 Sep 2020 01:57:10 |
| User entered '17 Sep 2020 20:53' | System | 18 Sep 2020 01:57:10 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '17 Sep 2020 14:45' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '18 Sep 2020 11:59' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 17 Sep 2020 16:09:36 |
| User entered 'Day 2' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-18T20:16:19', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'e64fb187-f11d-41b2-8979-4b95c7411412' | System | 19 Sep 2020 01:20:43 |
| User entered 'No interference with activity (1)' | System | 19 Sep 2020 01:20:43 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-18T20:16:24', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'e64fb187-f11d-41b2-8979-4b95c7411412' | System | 19 Sep 2020 01:20:43 |
| User entered 'Some interference with activity (2)' | System | 19 Sep 2020 01:20:43 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-18T20:16:29', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'e64fb187-f11d-41b2-8979-4b95c7411412' | System | 19 Sep 2020 01:20:43 |
| User entered 'Some interference with activity (2)' | System | 19 Sep 2020 01:20:43 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-18T20:16:33', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'e64fb187-f11d-41b2-8979-4b95c7411412' | System | 19 Sep 2020 01:20:43 |
| User entered 'None (0)' | System | 19 Sep 2020 01:20:43 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-18T20:16:36', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'e64fb187-f11d-41b2-8979-4b95c7411412' | System | 19 Sep 2020 01:20:43 |
| User entered 'None (0)' | System | 19 Sep 2020 01:20:43 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-18T20:16:40', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'e64fb187-f11d-41b2-8979-4b95c7411412' | System | 19 Sep 2020 01:20:43 |
| User entered 'No interference with activity (1)' | System | 19 Sep 2020 01:20:43 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-18T20:16:46', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'e64fb187-f11d-41b2-8979-4b95c7411412' | System | 19 Sep 2020 01:20:43 |
| User entered 'No (N)' | System | 19 Sep 2020 01:20:43 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-18T20:16:50', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'e64fb187-f11d-41b2-8979-4b95c7411412' | System | 19 Sep 2020 01:20:43 |
| User entered '18 Sep 2020 20:16' | System | 19 Sep 2020 01:20:43 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '18 Sep 2020 12:00' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '19 Sep 2020 11:59' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 17 Sep 2020 16:09:36 |
| User entered 'Day 3' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T00:03:08', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '7b1e3e7a-337b-4710-9d83-7c8f3942a8fd' | System | 20 Sep 2020 05:07:18 |
| User entered 'None (0)' | System | 20 Sep 2020 05:07:18 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T00:03:11', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '7b1e3e7a-337b-4710-9d83-7c8f3942a8fd' | System | 20 Sep 2020 05:07:18 |
| User entered 'None (0)' | System | 20 Sep 2020 05:07:18 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T00:03:14', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '7b1e3e7a-337b-4710-9d83-7c8f3942a8fd' | System | 20 Sep 2020 05:07:18 |
| User entered 'None (0)' | System | 20 Sep 2020 05:07:18 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T00:03:17', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '7b1e3e7a-337b-4710-9d83-7c8f3942a8fd' | System | 20 Sep 2020 05:07:18 |
| User entered 'None (0)' | System | 20 Sep 2020 05:07:18 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T00:03:19', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '7b1e3e7a-337b-4710-9d83-7c8f3942a8fd' | System | 20 Sep 2020 05:07:18 |
| User entered 'None (0)' | System | 20 Sep 2020 05:07:18 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T00:03:22', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '7b1e3e7a-337b-4710-9d83-7c8f3942a8fd' | System | 20 Sep 2020 05:07:18 |
| User entered 'None (0)' | System | 20 Sep 2020 05:07:18 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T00:03:25', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '7b1e3e7a-337b-4710-9d83-7c8f3942a8fd' | System | 20 Sep 2020 05:07:18 |
| User entered 'No (N)' | System | 20 Sep 2020 05:07:18 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T00:03:28', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '7b1e3e7a-337b-4710-9d83-7c8f3942a8fd' | System | 20 Sep 2020 05:07:18 |
| User entered '20 Sep 2020 00:03' | System | 20 Sep 2020 05:07:18 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '19 Sep 2020 12:00' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '20 Sep 2020 11:59' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 17 Sep 2020 16:09:36 |
| User entered 'Day 4' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T23:22:58', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '047219f5-3a79-460f-abef-5a7dae89990f' | System | 21 Sep 2020 04:27:09 |
| User entered 'None (0)' | System | 21 Sep 2020 04:27:09 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T23:23:00', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '047219f5-3a79-460f-abef-5a7dae89990f' | System | 21 Sep 2020 04:27:09 |
| User entered 'None (0)' | System | 21 Sep 2020 04:27:09 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T23:23:03', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '047219f5-3a79-460f-abef-5a7dae89990f' | System | 21 Sep 2020 04:27:09 |
| User entered 'None (0)' | System | 21 Sep 2020 04:27:09 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T23:23:05', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '047219f5-3a79-460f-abef-5a7dae89990f' | System | 21 Sep 2020 04:27:09 |
| User entered 'None (0)' | System | 21 Sep 2020 04:27:09 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T23:23:07', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '047219f5-3a79-460f-abef-5a7dae89990f' | System | 21 Sep 2020 04:27:09 |
| User entered 'None (0)' | System | 21 Sep 2020 04:27:09 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T23:23:09', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '047219f5-3a79-460f-abef-5a7dae89990f' | System | 21 Sep 2020 04:27:09 |
| User entered 'None (0)' | System | 21 Sep 2020 04:27:09 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T23:23:16', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '047219f5-3a79-460f-abef-5a7dae89990f' | System | 21 Sep 2020 04:27:09 |
| User entered 'No (N)' | System | 21 Sep 2020 04:27:09 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-20T23:23:19', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '047219f5-3a79-460f-abef-5a7dae89990f' | System | 21 Sep 2020 04:27:09 |
| User entered '20 Sep 2020 23:23' | System | 21 Sep 2020 04:27:09 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '20 Sep 2020 12:00' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '21 Sep 2020 11:59' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 17 Sep 2020 16:09:36 |
| User entered 'Day 5' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-21T23:46:13', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'df88f890-a009-494d-9794-9832215af4c6' | System | 22 Sep 2020 04:50:23 |
| User entered 'None (0)' | System | 22 Sep 2020 04:50:23 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-21T23:46:15', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'df88f890-a009-494d-9794-9832215af4c6' | System | 22 Sep 2020 04:50:23 |
| User entered 'None (0)' | System | 22 Sep 2020 04:50:23 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-21T23:46:17', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'df88f890-a009-494d-9794-9832215af4c6' | System | 22 Sep 2020 04:50:23 |
| User entered 'None (0)' | System | 22 Sep 2020 04:50:23 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-21T23:46:20', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'df88f890-a009-494d-9794-9832215af4c6' | System | 22 Sep 2020 04:50:23 |
| User entered 'None (0)' | System | 22 Sep 2020 04:50:23 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-21T23:46:22', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'df88f890-a009-494d-9794-9832215af4c6' | System | 22 Sep 2020 04:50:23 |
| User entered 'None (0)' | System | 22 Sep 2020 04:50:23 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-21T23:46:25', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'df88f890-a009-494d-9794-9832215af4c6' | System | 22 Sep 2020 04:50:23 |
| User entered 'None (0)' | System | 22 Sep 2020 04:50:23 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-21T23:46:30', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'df88f890-a009-494d-9794-9832215af4c6' | System | 22 Sep 2020 04:50:23 |
| User entered 'No (N)' | System | 22 Sep 2020 04:50:23 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-21T23:46:32', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'df88f890-a009-494d-9794-9832215af4c6' | System | 22 Sep 2020 04:50:23 |
| User entered '21 Sep 2020 23:46' | System | 22 Sep 2020 04:50:23 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '21 Sep 2020 12:00' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '22 Sep 2020 11:59' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 17 Sep 2020 16:09:36 |
| User entered 'Day 6' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-22T20:15:32', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '77aae1cc-8c60-4a85-9742-d7877371c21b' | System | 23 Sep 2020 01:19:44 |
| User entered 'None (0)' | System | 23 Sep 2020 01:19:44 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-22T20:15:34', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '77aae1cc-8c60-4a85-9742-d7877371c21b' | System | 23 Sep 2020 01:19:44 |
| User entered 'None (0)' | System | 23 Sep 2020 01:19:44 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-22T20:15:37', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '77aae1cc-8c60-4a85-9742-d7877371c21b' | System | 23 Sep 2020 01:19:44 |
| User entered 'None (0)' | System | 23 Sep 2020 01:19:44 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-22T20:15:40', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '77aae1cc-8c60-4a85-9742-d7877371c21b' | System | 23 Sep 2020 01:19:44 |
| User entered 'None (0)' | System | 23 Sep 2020 01:19:44 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-22T20:15:42', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '77aae1cc-8c60-4a85-9742-d7877371c21b' | System | 23 Sep 2020 01:19:44 |
| User entered 'None (0)' | System | 23 Sep 2020 01:19:44 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-22T20:15:45', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '77aae1cc-8c60-4a85-9742-d7877371c21b' | System | 23 Sep 2020 01:19:44 |
| User entered 'None (0)' | System | 23 Sep 2020 01:19:44 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-22T20:15:50', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '77aae1cc-8c60-4a85-9742-d7877371c21b' | System | 23 Sep 2020 01:19:44 |
| User entered 'No (N)' | System | 23 Sep 2020 01:19:44 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-22T20:15:53', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '77aae1cc-8c60-4a85-9742-d7877371c21b' | System | 23 Sep 2020 01:19:44 |
| User entered '22 Sep 2020 20:15' | System | 23 Sep 2020 01:19:44 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '22 Sep 2020 12:00' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '23 Sep 2020 11:59' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 17 Sep 2020 16:09:36 |
| User entered 'Day 7' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-23T23:38:21', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'da8e73a0-492e-49cb-be42-2e01c8984b67' | System | 24 Sep 2020 04:42:29 |
| User entered 'None (0)' | System | 24 Sep 2020 04:42:29 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-23T23:38:24', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'da8e73a0-492e-49cb-be42-2e01c8984b67' | System | 24 Sep 2020 04:42:29 |
| User entered 'None (0)' | System | 24 Sep 2020 04:42:29 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-23T23:38:26', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'da8e73a0-492e-49cb-be42-2e01c8984b67' | System | 24 Sep 2020 04:42:29 |
| User entered 'None (0)' | System | 24 Sep 2020 04:42:29 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-23T23:38:28', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'da8e73a0-492e-49cb-be42-2e01c8984b67' | System | 24 Sep 2020 04:42:29 |
| User entered 'None (0)' | System | 24 Sep 2020 04:42:29 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-23T23:38:30', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'da8e73a0-492e-49cb-be42-2e01c8984b67' | System | 24 Sep 2020 04:42:29 |
| User entered 'None (0)' | System | 24 Sep 2020 04:42:29 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-23T23:38:32', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'da8e73a0-492e-49cb-be42-2e01c8984b67' | System | 24 Sep 2020 04:42:29 |
| User entered 'None (0)' | System | 24 Sep 2020 04:42:29 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-23T23:38:36', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'da8e73a0-492e-49cb-be42-2e01c8984b67' | System | 24 Sep 2020 04:42:29 |
| User entered 'No (N)' | System | 24 Sep 2020 04:42:29 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-09-23T23:38:38', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'da8e73a0-492e-49cb-be42-2e01c8984b67' | System | 24 Sep 2020 04:42:29 |
| User entered '23 Sep 2020 23:38' | System | 24 Sep 2020 04:42:29 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '23 Sep 2020 12:00' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:53

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| User entered '24 Sep 2020 11:59' | System | 17 Sep 2020 16:09:36 |

US3292245

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) Kristy Trevino (b) (4) | 24 Sep 2020 16:06:02 |

US3292245

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '24 Sep 2020' | (b) (4) Kristy Trevino (b) (4) | 24 Sep 2020 16:06:02 |

US3292245

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Kristy Trevino (b) (4) | 24 Sep 2020 16:06:02 |

US3292245

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4) Kristy Trevino (b) (4) (b) (4) | 24 Sep 2020 16:06:02 |

US3292245

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) Kristy Trevino (b) (4) | 24 Sep 2020 16:06:31 |

US3292245

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User entered 'l' | System | 24 Sep 2020 16:06:31 |

US3292245

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 02 Oct 2020 21:02:32 |

US3292245

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '2 Oct 2020' | (b) (4), (b) (6) | 02 Oct 2020 21:02:32 |

US3292245

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 02 Oct 2020 21:02:32 |

US3292245

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4), (b) (6) | 02 Oct 2020 21:02:32 |

US3292245

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 02 Oct 2020 21:02:37 |

US3292245

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User entered 'l' | System | 02 Oct 2020 21:02:37 |

US3292245

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) Gerardo Pena (b) (4) | 15 Oct 2020 17:59:54 |

US3292245

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '10 Oct 2020' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 15 Oct 2020 17:59:54 |

US3292245

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Contact Not Made (CONTACT NOT MADE)' | (b) (4) Gerardo Pena (b) (4) | 15 Oct 2020 17:59:54 |

US3292245

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. | (b) (4) System | 15 Oct 2020 18:25:53 |
| Please review and reconcile.' (Site from System). | | |
| User entered 'Three attempts were made to contact subject, no answer, visit wasnot done' reason for change: New Information | Kristy Trevino (b) (4) | 15 Oct 2020 18:25:53 |
| User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. | (b) (4) System | 15 Oct 2020 17:59:54 |
| Please review and reconcile.' (Site from System). | | |
| User entered empty. | Gerardo Pena (b) (4) | 15 Oct 2020 17:59:54 |
| | (b) (4) | |

US3292245

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) Gerardo Pena (b) (4) | 15 Oct 2020 18:09:13 |

US3292245

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:46 |
| User entered 'l' | System | 15 Oct 2020 18:09:13 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:53

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered 'Yes (Y)' | (b) (4) Gerardo Pena (b) (4) | 15 Oct 2020 18:09:47 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:53

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '15 Oct 2020' | (b) (4) Gerardo Pena (b) (4) | 15 Oct 2020 18:09:47 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered 'Clinic (Clinic)' | (b) (4) Gerardo Pena (b) (4) | 15 Oct 2020 18:09:47 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:53

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'VISIT3' | System | 15 Oct 2020 18:09:47 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered 'Yes (Y)' | (b) (4) Gerardo Pena (b) (4) | 15 Oct 2020 18:11:51 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '15 Oct 2020' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 15 Oct 2020 18:11:51 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '12:17' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 15 Oct 2020 18:11:51 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered '15 Oct 2020 12:17' | System | 15 Oct 2020 18:11:51 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '36.6' C | (b) (4) Gerardo Pena (b) (4) | 15 Oct 2020 18:11:51 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered 'Oral (Oral)' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 15 Oct 2020 18:11:51 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered empty. | (b) (4) Gerardo Pena (b) (4) (b) (4) | 15 Oct 2020 18:11:51 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '69' | (b) (4) Gerardo Pena (b) (4) (b) (4) | 15 Oct 2020 18:11:51 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'bpm' | System | 15 Oct 2020 18:11:51 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '12' | (b) (4) Gerardo Pena (b) (4) | 15 Oct 2020 18:11:51 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'breaths/min' | System | 15 Oct 2020 18:11:51 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '104' | (b) (4) Gerardo Pena (b) (4) | 15 Oct 2020 18:11:51 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'mmHg' | System | 15 Oct 2020 18:11:51 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '63' | (b) (4) Gerardo Pena (b) (4) | 15 Oct 2020 18:11:51 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'mmHg' | System | 15 Oct 2020 18:11:51 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:53

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered 'No (N)' | (b) (4) Gerardo Pena (b) (4) | 15 Oct 2020 18:11:55 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:53

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered empty. | (b) (4) Gerardo Pena (b) (4) | 15 Oct 2020 18:11:55 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:53

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered 'Yes (Y)' | (b) (4) Gerardo Pena (b) (4) | 15 Oct 2020 18:12:09 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:53

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '15 Oct 2020' | (b) (4) Gerardo Pena (b) (4) | 15 Oct 2020 18:12:09 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:53

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered '12:25' | (b) (4) Gerardo Pena (b) (4) | 15 Oct 2020 18:12:09 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:53

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered '15 Oct 2020 12:25' | System | 15 Oct 2020 18:12:09 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:20 |
| User entered 'Yes (Y)' | (b) (4) Gerardo Pena (b) (4) | 15 Oct 2020 18:12:14 |

US3292245

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'I' | System | 15 Oct 2020 18:12:14 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 64' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-10-21T13:18:12', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'f15ccff-45d2-4f08-ab8f-a6e988131a65' | System | 21 Oct 2020 18:22:39 |
| User entered 'No (N)' | System | 21 Oct 2020 18:22:39 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-10-21T13:18:23', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'f15ccff-45d2-4f08-ab8f-a6e988131a65' | System | 21 Oct 2020 18:22:39 |
| User entered 'No (N)' | System | 21 Oct 2020 18:22:39 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-10-21T13:18:28', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'f15ccff-45d2-4f08-ab8f-a6e988131a65' | System | 21 Oct 2020 18:22:39 |
| User entered '21 Oct 2020 13:18:28' | System | 21 Oct 2020 18:22:39 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered '20 Oct 2020 00:01' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered '24 Oct 2020 23:59' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 71' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-10-30T22:21:30', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'e7da5bac-a642-4de2-8de5-39d6667a3818' | System | 31 Oct 2020 03:25:57 |
| User entered 'No (N)' | System | 31 Oct 2020 03:25:57 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-10-30T22:21:40', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'e7da5bac-a642-4de2-8de5-39d6667a3818' | System | 31 Oct 2020 03:25:57 |
| User entered 'No (N)' | System | 31 Oct 2020 03:25:57 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-10-30T22:21:48', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'e7da5bac-a642-4de2-8de5-39d6667a3818' | System | 31 Oct 2020 03:25:57 |
| User entered '30 Oct 2020 22:21:48' | System | 31 Oct 2020 03:25:57 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered '27 Oct 2020 00:01' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered '31 Oct 2020 23:59' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 78' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Chills](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Cough](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Fatigue](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Muscle aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Body aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Headache](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[New loss of taste](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[New loss of smell](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Sore throat](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Congestion](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Runny nose](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Nausea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Vomiting](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered '03 Nov 2020 00:01' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:50:37 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered '07 Nov 2020 23:59' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered 'Day 92' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-11-17T00:02:34', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'f2bb2bd8-6a7d-405b-a42e-9fb5b751f9f5' | System | 17 Nov 2020 06:07:11 |
| User entered 'No (N)' | System | 17 Nov 2020 06:07:11 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-11-17T00:02:51', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'f2bb2bd8-6a7d-405b-a42e-9fb5b751f9f5' | System | 17 Nov 2020 06:07:11 |
| User entered 'No (N)' | System | 17 Nov 2020 06:07:11 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-11-17T00:02:56', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'f2bb2bd8-6a7d-405b-a42e-9fb5b751f9f5' | System | 17 Nov 2020 06:07:11 |
| User entered '17 Nov 2020 00:02:56' | System | 17 Nov 2020 06:07:11 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered '17 Nov 2020 00:01' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:06:26 |
| Data entry locked. | System | 20 Aug 2020 17:54:17 |
| User entered '21 Nov 2020 23:59' | System | 20 Aug 2020 17:54:17 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[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 (db851dc3780fe10b)', Time: '2020-11-25T14:45:47', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '76fea4c1-3057-451f-8f01-d983b9d3b460' | System | 25 Nov 2020 20:50:12 |
| User entered 'No (N)' | System | 25 Nov 2020 20:50:12 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Have you been exposed to someone with 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 (db851dc3780fe10b)', Time: '2020-11-25T14:45:54', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '76fea4c1-3057-451f-8f01-d983b9d3b460' | System | 25 Nov 2020 20:50:12 |
| User entered 'No (N)' | System | 25 Nov 2020 20:50:12 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-11-25T14:45:58', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '76fea4c1-3057-451f-8f01-d983b9d3b460' User entered '25 Nov 2020 14:45:58' | System | 25 Nov 2020 20:50:12 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '21 Nov 2020 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '25 Nov 2020 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[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 (db851dc3780fe10b)', Time: '2020-11-28T11:30:31', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '0e69257c-eebb-4d41-970c-f2ddeb1eb6a7' | System | 28 Nov 2020 17:34:54 |
| User entered 'No (N)' | System | 28 Nov 2020 17:34:54 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Have you been exposed to someone with 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 (db851dc3780fe10b)', Time: '2020-11-28T11:30:37', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '0e69257c-eebb-4d41-970c-f2ddeb1eb6a7' | System | 28 Nov 2020 17:34:54 |
| User entered 'No (N)' | System | 28 Nov 2020 17:34:54 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-11-28T11:30:40', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '0e69257c-eebb-4d41-970c-f2ddeb1eb6a7' | System | 28 Nov 2020 17:34:54 |
| User entered '28 Nov 2020 11:30:40' | System | 28 Nov 2020 17:34:54 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '28 Nov 2020 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '02 Dec 2020 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[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 (db851dc3780fe10b)', Time: '2020-12-05T00:01:11', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '5579a480-89d8-4a8f-8d0c-9f369c3002a7' | System | 05 Dec 2020 06:06:17 |
| User entered 'No (N)' | System | 05 Dec 2020 06:06:17 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

Have you been exposed to someone with 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 (db851dc3780fe10b)', Time: '2020-12-05T00:01:35', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '5579a480-89d8-4a8f-8d0c-9f369c3002a7' | System | 05 Dec 2020 06:06:17 |
| User entered 'No (N)' | System | 05 Dec 2020 06:06:17 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-12-05T00:01:44', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '5579a480-89d8-4a8f-8d0c-9f369c3002a7' User entered '05 Dec 2020 00:01:44' | System | 05 Dec 2020 06:06:17 |
| | System | 05 Dec 2020 06:06:17 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '05 Dec 2020 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '09 Dec 2020 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[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 (db851dc3780fe10b)', Time: '2020-12-12T21:03:35', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '31112cd9-c657-41fe-b60d-0718e863293a' | System | 13 Dec 2020 03:08:21 |
| User entered 'No (N)' | System | 13 Dec 2020 03:08:21 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

Have you been exposed to someone with 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 (db851dc3780fe10b)', Time: '2020-12-12T21:03:45', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '31112cd9-c657-41fe-b60d-0718e863293a' | System | 13 Dec 2020 03:08:21 |
| User entered 'No (N)' | System | 13 Dec 2020 03:08:21 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-12-12T21:03:49', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '31112cd9-c657-41fe-b60d-0718e863293a' User entered '12 Dec 2020 21:03:49' | System | 13 Dec 2020 03:08:21 |
| | System | 13 Dec 2020 03:08:21 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '12 Dec 2020 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '16 Dec 2020 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[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 (db851dc3780fe10b)', Time: '2020-12-21T20:07:02', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '30c7682d-5fdb-407e-9f01-0f321eb4acd6' | System | 22 Dec 2020 02:11:46 |
| User entered 'No (N)' | System | 22 Dec 2020 02:11:46 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Have you been exposed to someone with 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 (db851dc3780fe10b)', Time: '2020-12-21T20:07:07', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '30c7682d-5fdb-407e-9f01-0f321eb4acd6' | System | 22 Dec 2020 02:11:46 |
| User entered 'No (N)' | System | 22 Dec 2020 02:11:46 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-12-21T20:07:10', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '30c7682d-5fdb-407e-9f01-0f321eb4acd6' | System | 22 Dec 2020 02:11:46 |
| User entered '21 Dec 2020 20:07:10' | System | 22 Dec 2020 02:11:46 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '19 Dec 2020 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '23 Dec 2020 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[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 (db851dc3780fe10b)', Time: '2020-12-29T21:41:32', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '91031857-4b76-4a10-9888-3b02ee0cd701' | System | 30 Dec 2020 03:46:52 |
| User entered 'No (N)' | System | 30 Dec 2020 03:46:52 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Have you been exposed to someone with 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 (db851dc3780fe10b)', Time: '2020-12-29T21:41:34', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '91031857-4b76-4a10-9888-3b02ee0cd701' | System | 30 Dec 2020 03:46:52 |
| User entered 'No (N)' | System | 30 Dec 2020 03:46:52 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2020-12-29T21:41:39', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '91031857-4b76-4a10-9888-3b02ee0cd701' | System | 30 Dec 2020 03:46:52 |
| User entered '29 Dec 2020 21:41:39' | System | 30 Dec 2020 03:46:52 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '26 Dec 2020 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '30 Dec 2020 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '02 Jan 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '06 Jan 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '09 Jan 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '13 Jan 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[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 (db851dc3780fe10b)', Time: '2021-01-16T13:04:16', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '0f9ffd02-145b-4000-9fc3-9e4ab3c307af' | System | 16 Jan 2021 19:09:15 |
| User entered 'No (N)' | System | 16 Jan 2021 19:09:15 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Have you been exposed to someone with 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 (db851dc3780fe10b)', Time: '2021-01-16T13:04:25', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '0f9ffd02-145b-4000-9fc3-9e4ab3c307af' | System | 16 Jan 2021 19:09:15 |
| User entered 'No (N)' | System | 16 Jan 2021 19:09:15 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2021-01-16T13:04:29', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '0f9ffd02-145b-4000-9fc3-9e4ab3c307af' User entered '16 Jan 2021 13:04:29' | System | 16 Jan 2021 19:09:15 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '16 Jan 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '20 Jan 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[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 (db851dc3780fe10b)', Time: '2021-01-25T15:59:02', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '4802ea72-c34b-461e-a8ab-d0ce27503e1d' | System | 25 Jan 2021 22:04:01 |
| User entered 'No (N)' | System | 25 Jan 2021 22:04:01 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Have you been exposed to someone with 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 (db851dc3780fe10b)', Time: '2021-01-25T15:59:09', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '4802ea72-c34b-461e-a8ab-d0ce27503e1d' | System | 25 Jan 2021 22:04:01 |
| User entered 'No (N)' | System | 25 Jan 2021 22:04:01 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2021-01-25T15:59:12', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '4802ea72-c34b-461e-a8ab-d0ce27503e1d' User entered '25 Jan 2021 15:59:12' | System | 25 Jan 2021 22:04:01 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '23 Jan 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '27 Jan 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[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 (db851dc3780fe10b)', Time: '2021-02-03T23:20:32', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '3f340ff2-5dfd-41e1-bf5f-e50f0c4b3231' | System | 04 Feb 2021 05:25:35 |
| User entered 'No (N)' | System | 04 Feb 2021 05:25:35 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Have you been exposed to someone with 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 (db851dc3780fe10b)', Time: '2021-02-03T23:20:39', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '3f340ff2-5dfd-41e1-bf5f-e50f0c4b3231' | System | 04 Feb 2021 05:25:35 |
| User entered 'No (N)' | System | 04 Feb 2021 05:25:35 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2021-02-03T23:20:42', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '3f340ff2-5dfd-41e1-bf5f-e50f0c4b3231' User entered '03 Feb 2021 23:20:42' | System | 04 Feb 2021 05:25:35 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '30 Jan 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '03 Feb 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[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 (db851dc3780fe10b)', Time: '2021-02-06T00:58:34', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'f760c621-25de-4b6d-8c8d-e77b3f618383' | System | 06 Feb 2021 07:03:35 |
| User entered 'No (N)' | System | 06 Feb 2021 07:03:35 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Have you been exposed to someone with 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 (db851dc3780fe10b)', Time: '2021-02-06T00:58:41', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'f760c621-25de-4b6d-8c8d-e77b3f618383' | System | 06 Feb 2021 07:03:35 |
| User entered 'No (N)' | System | 06 Feb 2021 07:03:35 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2021-02-06T00:58:43', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'f760c621-25de-4b6d-8c8d-e77b3f618383' User entered '06 Feb 2021 00:58:43' | System | 06 Feb 2021 07:03:35 |
| | System | 06 Feb 2021 07:03:35 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '06 Feb 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '10 Feb 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[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 (db851dc3780fe10b)', Time: '2021-02-16T11:08:48', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '79777315-731e-4b5d-9ce7-84ca3b6f121e' | System | 16 Feb 2021 17:20:14 |
| User entered 'No (N)' | System | 16 Feb 2021 17:20:14 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Have you been exposed to someone with 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 (db851dc3780fe10b)', Time: '2021-02-16T11:08:57', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '79777315-731e-4b5d-9ce7-84ca3b6f121e' | System | 16 Feb 2021 17:20:14 |
| User entered 'No (N)' | System | 16 Feb 2021 17:20:14 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2021-02-16T11:08:59', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '79777315-731e-4b5d-9ce7-84ca3b6f121e' User entered '16 Feb 2021 11:08:59' | System | 16 Feb 2021 17:20:14 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '13 Feb 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '17 Feb 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[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 (db851dc3780fe10b)', Time: '2021-02-20T00:49:56', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'a7f7db98-251e-4715-81e9-57d2a0c4e687' | System | 20 Feb 2021 06:55:21 |
| User entered 'No (N)' | System | 20 Feb 2021 06:55:21 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Have you been exposed to someone with 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 (db851dc3780fe10b)', Time: '2021-02-20T00:50:15', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'a7f7db98-251e-4715-81e9-57d2a0c4e687' | System | 20 Feb 2021 06:55:21 |
| User entered 'No (N)' | System | 20 Feb 2021 06:55:21 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2021-02-20T00:50:20', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'a7f7db98-251e-4715-81e9-57d2a0c4e687' User entered '20 Feb 2021 00:50:20' | System | 20 Feb 2021 06:55:21 |
| | System | 20 Feb 2021 06:55:21 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '20 Feb 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '24 Feb 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '27 Feb 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '03 Mar 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '06 Mar 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '10 Mar 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '13 Mar 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '17 Mar 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[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 (db851dc3780fe10b)', Time: '2021-03-20T11:33:03-05:00', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '3e66c771-1420-412e-ba05-a7d4242e6578' | System | 20 Mar 2021 16:38:41 |
| User entered 'No (N)' | System | 20 Mar 2021 16:38:41 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

Have you been exposed to someone with 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 (db851dc3780fe10b)', Time: '2021-03-20T11:33:24-05:00', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '3e66c771-1420-412e-ba05-a7d4242e6578' | System | 20 Mar 2021 16:38:41 |
| User entered 'No (N)' | System | 20 Mar 2021 16:38:41 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2021-03-20T11:33:29-05:00', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: '3e66c771-1420-412e-ba05-a7d4242e6578' | System | 20 Mar 2021 16:38:41 |
| User entered '20 Mar 2021 11:33:29' | System | 20 Mar 2021 16:38:41 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '20 Mar 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '24 Mar 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '27 Mar 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '31 Mar 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '03 Apr 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '07 Apr 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[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 (db851dc3780fe10b)', Time: '2021-04-10T18:11:13-05:00', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'a672598c-184d-42ec-8d45-d92c4ab2095f' User entered 'No (N)' | System | 10 Apr 2021 23:16:49 |
| | System | 10 Apr 2021 23:16:49 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

Have you been exposed to someone with 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 (db851dc3780fe10b)', Time: '2021-04-10T18:11:23-05:00', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'a672598c-184d-42ec-8d45-d92c4ab2095f' User entered 'No (N)' | System | 10 Apr 2021 23:16:49 |
| | System | 10 Apr 2021 23:16:49 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2021-04-10T18:11:30-05:00', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'a672598c-184d-42ec-8d45-d92c4ab2095f' User entered '10 Apr 2021 18:11:30' | System | 10 Apr 2021 23:16:49 |
| | System | 10 Apr 2021 23:16:49 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '10 Apr 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '14 Apr 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '17 Apr 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '21 Apr 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '24 Apr 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '28 Apr 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '01 May 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '05 May 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '08 May 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '12 May 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '15 May 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '19 May 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '22 May 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '26 May 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '29 May 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '02 Jun 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '05 Jun 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '09 Jun 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '12 Jun 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '16 Jun 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '19 Jun 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '23 Jun 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '26 Jun 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '30 Jun 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '03 Jul 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '07 Jul 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '10 Jul 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '14 Jul 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '17 Jul 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '21 Jul 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '24 Jul 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '28 Jul 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '31 Jul 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '04 Aug 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '07 Aug 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '11 Aug 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '14 Aug 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '18 Aug 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '21 Aug 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '25 Aug 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '28 Aug 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '01 Sep 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '04 Sep 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '08 Sep 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '11 Sep 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '15 Sep 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '18 Sep 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '22 Sep 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '25 Sep 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '29 Sep 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '02 Oct 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '06 Oct 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '09 Oct 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '13 Oct 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '16 Oct 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '20 Oct 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '23 Oct 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '27 Oct 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '30 Oct 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '03 Nov 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '06 Nov 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '10 Nov 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '13 Nov 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '17 Nov 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '20 Nov 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '24 Nov 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '27 Nov 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '01 Dec 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '04 Dec 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '08 Dec 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '11 Dec 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '15 Dec 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '18 Dec 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '22 Dec 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '25 Dec 2021 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '29 Dec 2021 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '01 Jan 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '05 Jan 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '08 Jan 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '12 Jan 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '15 Jan 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '19 Jan 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '22 Jan 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '26 Jan 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '29 Jan 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '02 Feb 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '05 Feb 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '09 Feb 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '12 Feb 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '16 Feb 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '19 Feb 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '23 Feb 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '26 Feb 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '02 Mar 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '05 Mar 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '09 Mar 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '12 Mar 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '16 Mar 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '19 Mar 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '23 Mar 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '26 Mar 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '30 Mar 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '02 Apr 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '06 Apr 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '09 Apr 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '13 Apr 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '16 Apr 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '20 Apr 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '23 Apr 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '27 Apr 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '30 Apr 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '04 May 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '07 May 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '11 May 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '14 May 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '18 May 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '21 May 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '25 May 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '28 May 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '01 Jun 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '04 Jun 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '08 Jun 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '11 Jun 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '15 Jun 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '18 Jun 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '22 Jun 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '25 Jun 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '29 Jun 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '02 Jul 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '06 Jul 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '09 Jul 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '13 Jul 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '16 Jul 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '20 Jul 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '23 Jul 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '27 Jul 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '30 Jul 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '03 Aug 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '06 Aug 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '10 Aug 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '13 Aug 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '17 Aug 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '20 Aug 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '24 Aug 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '27 Aug 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '31 Aug 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '03 Sep 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '07 Sep 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '10 Sep 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '14 Sep 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '17 Sep 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '21 Sep 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '24 Sep 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '28 Sep 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '01 Oct 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '05 Oct 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '08 Oct 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '12 Oct 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '15 Oct 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '19 Oct 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '22 Oct 2022 00:01' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:53

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:50:37 |
| Amendment Manager: User entered '26 Oct 2022 23:59' | System | 19 Nov 2020 23:50:37 |

US3292245

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:27:53

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 09:34:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2021-03-10T12:15:03-06:00', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'a5590744-8403-4752-87ce-ad11c5f9577c' | System | 10 Mar 2021 18:20:20 |
| User entered 'No (N)' | System | 10 Mar 2021 18:20:20 |

US3292245

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:27:53

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:34:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db851dc3780fe10b)', Time: '2021-03-10T12:15:09-06:00', User OID: 'PatientReportedOutcome (US3292245)', ODM File OID: 'a5590744-8403-4752-87ce-ad11c5f9577c' User entered '10 Mar 2021 12:15:09' | System | 10 Mar 2021 18:20:20 |
| | System | 10 Mar 2021 18:20:20 |

US3292245

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Nov 2020 22:19:56 |

US3292245

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '12 Nov 2020' | (b) (4), (b) (6) | 16 Nov 2020 22:19:56 |

US3292245

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 16 Nov 2020 22:19:56 |

US3292245

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4), (b) (6) | 16 Nov 2020 22:19:56 |

US3292245

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Nov 2020 22:20:05 |

US3292245

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 02:21:49 |
| User entered 'l' | System | 16 Nov 2020 22:20:05 |

US3292245

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:35:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 17 Dec 2020 15:29:02 |

US3292245

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:35:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '16 Dec 2020' | (b) (4), (b) (6) | 17 Dec 2020 15:29:02 |

US3292245

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:35:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 17 Dec 2020 15:29:02 |

US3292245

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:35:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4), (b) (6) | 17 Dec 2020 15:29:02 |

US3292245

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:35:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 17 Dec 2020 15:29:12 |

US3292245

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:35:01 |
| User entered 'l' | System | 17 Dec 2020 15:29:12 |

US3292245

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:35:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) Gerardo Pena (b) (4) | 18 Jan 2021 22:25:19 |

US3292245

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:35:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '15 Jan 2021' | (b) (4) Gerardo Pena (b) (4) | 18 Jan 2021 22:25:19 |

US3292245

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:35:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Gerardo Pena (b) (4) | 18 Jan 2021 22:25:19 |

US3292245

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:35:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered empty. | (b) (4) Gerardo Pena (b) (4) (b) (4) | 18 Jan 2021 22:25:19 |

US3292245

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:35:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) Gerardo Pena (b) (4) | 18 Jan 2021 22:25:58 |

US3292245

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:35:01 |
| User entered 'l' | System | 18 Jan 2021 22:25:58 |

US3292245

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:35:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 18 Feb 2021 03:45:26 |

US3292245

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:35:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '17 Feb 2021' | (b) (4), (b) (6) | 18 Feb 2021 03:45:26 |

US3292245

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:35:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Contact Not Made (CONTACT NOT MADE)' | (b) (4), (b) (6) | 18 Feb 2021 03:45:26 |

US3292245

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|-------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:35:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '3 attempts no answer' | (b) (4), (b) (6) | 18 Feb 2021 03:45:26 |

US3292245

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:35:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 18 Feb 2021 03:45:34 |

US3292245

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:35:02 |
| User entered 'l' | System | 18 Feb 2021 03:45:34 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:53

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:49:02 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 19:45:53 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:49:02 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 19:45:53 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:49:02 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 19:45:53 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:53

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'VISIT4' | System | 16 Apr 2021 19:45:53 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:49:02 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 19:45:58 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:49:02 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 19:45:58 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:49:02 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 19:45:58 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Apr 2021 19:45:58 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:49:02 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 19:45:58 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:49:02 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 19:45:58 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:49:02 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 19:45:58 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:49:02 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 19:45:58 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Apr 2021 19:45:58 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:49:02 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 19:45:58 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Apr 2021 19:45:58 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:49:02 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 19:45:58 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Apr 2021 19:45:58 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:49:02 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 19:45:58 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:53

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Apr 2021 19:45:58 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:53

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:49:02 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 19:46:02 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:53

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:49:02 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 19:46:02 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:53

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:49:02 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 19:46:06 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:53

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:49:02 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 19:46:06 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:53

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:49:02 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 19:46:06 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:53

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Apr 2021 19:46:06 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:49:02 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 19:46:10 |

US3292245

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 16 Apr 2021 19:46:10 |

US3292245

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:49:02 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 15:50:19 |

US3292245

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:49:02 |
| User entered '16 Apr 2021' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 15:50:19 |

US3292245

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:49:02 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 15:50:19 |

US3292245

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:53

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:49:02 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 15:50:19 |

US3292245

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:49:02 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 15:50:22 |

US3292245

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:53

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 19 Apr 2021 15:50:22 |

US3292245

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

Form: Visit Date

Generated On: 09 Jun 2021 16:27:53

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) Dawn Killian (b) (4) | 28 Jan 2021 20:13:59 |

US3292245

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

Form: Visit Date

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '28 Jan 2021' | (b) (4) Dawn Killian (b) (4) | 28 Jan 2021 20:13:59 |

US3292245

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

Form: Visit Date

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Clinic (Clinic)' | (b) (4) Dawn Killian (b) (4) | 28 Jan 2021 20:13:59 |

US3292245

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

Form: Visit Date

Generated On: 09 Jun 2021 16:27:53

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered 'UNBLND_DECIDE' | System | 28 Jan 2021 20:13:59 |

US3292245

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

Form: Unblinding

Generated On: 09 Jun 2021 16:27:53

Date of updated informed consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '28 Jan 2021' | (b) (4) Dawn Killian (b) (4) | 28 Jan 2021 20:14:14 |

US3292245

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

Form: Unblinding

Generated On: 09 Jun 2021 16:27:53

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '0' WR# 5295537 | (b) (4) | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 06:00:13 |

US3292245

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

Form: Unblinding

Generated On: 09 Jun 2021 16:27:53

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) Dawn Killian (b) (4) | 28 Jan 2021 20:14:14 |

US3292245

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

Form: Unblinding

Generated On: 09 Jun 2021 16:27:53

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537 | (b) (4) System | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 06:00:13 |

US3292245

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

Form: Unblinding

Generated On: 09 Jun 2021 16:27:53

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '28 Jan 2021' | (b) (4) Dawn Killian (b) (4) | 28 Jan 2021 20:14:14 |

US3292245

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

Form: Unblinding

Generated On: 09 Jun 2021 16:27:53

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|--------------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4) Dawn Killian (b) (4) | 28 Jan 2021 20:14:14 |

US3292245

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

Form: Unblinding

Generated On: 09 Jun 2021 16:27:53

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|--------------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4) Dawn Killian (b) (4) | 28 Jan 2021 20:14:14 |

US3292245

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

Form: Unblinding

Generated On: 09 Jun 2021 16:27:53

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|--------------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4) Dawn Killian (b) (4) | 28 Jan 2021 20:14:14 |

US3292245

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

Form: Unblinding

Generated On: 09 Jun 2021 16:27:53

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4) Dawn Killian (b) (4) | 28 Jan 2021 20:14:14 |

US3292245

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

Form: Unblinding

Generated On: 09 Jun 2021 16:27:53

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered empty. | System | 28 Jan 2021 20:14:14 |

US3292245

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

Form: Unblinding

Generated On: 09 Jun 2021 16:27:53

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered empty. | System | 28 Jan 2021 20:14:14 |

US3292245

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:53

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) Dawn Killian (b) (4) | 28 Jan 2021 20:14:28 |

US3292245

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:53

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '28 Jan 2021' | (b) (4) Dawn Killian (b) (4) | 28 Jan 2021 20:14:28 |

US3292245

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:53

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '10:58' | (b) (4) Dawn Killian (b) (4) | 28 Jan 2021 20:14:28 |

US3292245

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:53

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered '28 Jan 2021 10:58' | System | 28 Jan 2021 20:14:28 |

US3292245

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:27:53

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'Yes (Y)' | (b) (4) Dawn Killian (b) (4) | 28 Jan 2021 20:14:36 |

US3292245

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:27:53

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '28 Jan 2021' | (b) (4) Dawn Killian (b) (4) | 28 Jan 2021 20:14:36 |

US3292245

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:27:53

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered '11:06' | (b) (4) Dawn Killian (b) (4) | 28 Jan 2021 20:14:36 |

US3292245

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:27:53

[Collection Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:35:11 |
| User entered '28 Jan 2021 11:06' | System | 28 Jan 2021 20:14:36 |

US3292245

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:27:53

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 13:18:28 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:49:02 |
| Signature has been broken. | (b) (4) | 19 Apr 2021 15:50:46 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 19 Apr 2021 15:50:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4) | |
| | Dawn Killian (b) (4) | 03 Feb 2021 22:25:47 |
| | (b) (4) | |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[AEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:32:55 |
| User entered 'USA-US072-2021-mRNA-1273-P301000021' | System | 29 Apr 2021 13:31:15 |
| User entered 'New' | (b) (4), (b) (6) | 29 Apr 2021 13:31:15 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 19 Apr 2021 16:12:29 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Apr 2021 16:12:29 |
| Data point term sent to Coder | System | 19 Apr 2021 16:08:10 |
| User entered 'Prostate Cancer' | (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4) System | 22 Apr 2021 16:45:54 |
| User entered '01 Nov 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Apr 2021 16:45:54 |
| Comment added 'date is unknow Nov 2020'. | | 19 Apr 2021 16:08:34 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 19 Apr 2021 16:08:04 |
| User entered 'un Nov 2020' (non-conformant). | (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[Severity](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| User closed query 'Per MM: please confirm seriousness assessment. ' (Site from DM). | (b) (4), (b) (6) | 29 Apr 2021 09:46:25 |
| Query 'Per MM: please confirm seriousness assessment. ' answered with 'PI has determined AE is an SAE' (Site from DM). | (b) (4), (b) (6) | 28 Apr 2021 17:32:39 |
| User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System | 28 Apr 2021 17:32:21 |
| User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System | 28 Apr 2021 17:30:13 |
| Signature has been broken. | (b) (4), (b) (6) | 28 Apr 2021 17:30:13 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Apr 2021 17:30:13 |
| User opened query 'Per MM: please confirm seriousness assessment. ' (Site from DM). | Doug Dunford (b) (4) (b) (4) | 26 Apr 2021 00:22:34 |
| User signature succeeded. | Douglas Denham (b) (4) (b) (4) | 23 Apr 2021 18:33:29 |
| User entered 'No (N)' | (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[Other medically important event](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Signature has been broken. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Apr 2021 17:32:21 |
| User entered '1' reason for change: Data Entry Error | | 28 Apr 2021 17:32:21 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User entered '0' | (b) (4) | |
| | (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) System | 22 Apr 2021 16:43:30 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 22 Apr 2021 16:43:30 |
| User entered 'Not Related (NOT RELATED)' reason for change: New Information | (b) (4), (b) (6) | 22 Apr 2021 16:43:30 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Apr 2021 16:08:04 |
| User entered empty. | (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) System | 22 Apr 2021 16:43:30 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 22 Apr 2021 16:43:30 |
| User entered 'Not Related (NOT RELATED)' reason for change: New Information | (b) (4), (b) (6) | 22 Apr 2021 16:43:30 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Apr 2021 16:08:04 |
| User entered empty. | (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User entered 'None (NONE)' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

None

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 23 Apr 2021 18:33:29 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 28 Apr 2021 17:30:13 |
| User entered '0' | System | 19 Apr 2021 16:08:04 |

US3292245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 19 Apr 2021 16:08:04 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 13:18:28 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User closed query 'Per CDM: Please update medication used for dairy dose 2 day 2' (Site from DM). | (b) (4), (b) (6) | 03 Nov 2020 22:49:52 |
| Query 'Per CDM: Please update medication used for dairy dose 2 day 2' answered with 'subject was called and no meds taken; subject hit button in error' (Site from DM). | Dawn Killian (b) (4) | 12 Oct 2020 19:14:47 |
| User opened query 'Per CDM: Please update medication used for dairy dose 2 day 2' (Site from DM). | (b) (4), (b) (6) | 29 Sep 2020 11:10:47 |
| User entered 'Yes (Y)' | | 21 Aug 2020 18:33:20 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:53

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 21 Aug 2020 18:36:17 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 21 Aug 2020 18:36:17 |
| Data point term sent to Coder | System | 21 Aug 2020 18:35:27 |
| User entered 'Multivitamin' | (b) (4), (b) (6) | 21 Aug 2020 18:35:05 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:53

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:35:05 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:53

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Nutritional supplement' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:35:05 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:53

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:35:05 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:53

[Dose unit](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'tablet (TABLET)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:35:05 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:53

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:35:05 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:53

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'once daily (QD)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:35:05 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:53

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:35:05 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:53

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:35:05 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:53

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:35:05 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'un UNK 2000' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:35:05 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:53

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:35:05 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:53

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:35:05 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:53

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:35:05 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:53

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:35:05 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:53

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 21 Aug 2020 18:35:05 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 21 Aug 2020 18:35:05 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 18:35:05 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:53

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: GLUCOSAMINE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 21 Aug 2020 18:38:23 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 18:38:23 |
| Data point term sent to Coder | System | 21 Aug 2020 18:37:31 |
| User entered 'Glucosamine' | (b) (4), (b) (6) | 21 Aug 2020 18:36:44 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:53

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:36:44 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:53

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Nutritional supplement' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:36:44 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:53

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '500' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:36:44 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:53

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:36:44 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:53

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:36:44 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:53

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'twice daily (BID)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:36:44 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:53

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:36:44 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:53

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:36:44 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:53

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:36:44 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:53

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'un UNK 2000' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:36:44 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:53

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:36:44 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:53

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:36:44 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:53

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:36:44 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:53

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:36:44 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:53

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 21 Aug 2020 18:36:44 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 21 Aug 2020 18:36:44 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 18:36:44 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:53

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: COENZYME Q10 [UBIDECARENONE] - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 21 Aug 2020 18:40:17 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 21 Aug 2020 18:40:17 |
| Data point term sent to Coder | System | 21 Aug 2020 18:39:47 |
| User entered 'Coenzyme Q10' | (b) (4), (b) (6) | 21 Aug 2020 18:39:13 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:53

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:39:13 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:53

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Nutritional supplement' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:39:13 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:53

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '400' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:39:13 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:53

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:39:13 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:53

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:39:13 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:53

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'once daily (QD)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:39:13 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:53

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:39:13 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:53

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:39:13 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:53

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:39:13 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:53

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'un UNK 2015' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:39:13 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:53

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:39:13 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:53

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:39:13 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:53

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:39:13 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:53

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:39:13 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:53

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 21 Aug 2020 18:39:13 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 21 Aug 2020 18:39:13 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 18:39:13 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:53

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, PRODUCT: CETYL MYRISTOLEATE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 23 Aug 2020 13:16:35 |
| 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 Aug 2020 13:16:35 |
| Data point term sent to Coder | System | 21 Aug 2020 18:41:51 |
| User entered 'Cetyl myristoleate' | (b) (4), (b) (6) | 21 Aug 2020 18:41:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:53

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:41:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:53

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Nutritional supplement' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:41:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:53

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:41:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:53

[Dose unit](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'tablet (TABLET)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:41:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:53

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:41:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:53

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'once daily (QD)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:41:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:53

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:41:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:53

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:41:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:53

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:41:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'un Apr 2020' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:41:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:53

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:41:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:53

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:41:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:53

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:41:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:53

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:41:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:53

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 21 Aug 2020 18:41:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 21 Aug 2020 18:41:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 18:41:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:53

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HERBAL CHOLESTEROL AND TRIGLYCERIDE REDUCERS, PRODUCT: KRILL OIL - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 21 Aug 2020 18:43:26 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 21 Aug 2020 18:43:26 |
| Data point term sent to Coder | System | 21 Aug 2020 18:42:53 |
| User entered 'Krill oil' | (b) (4), (b) (6) | 21 Aug 2020 18:42:14 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:53

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:42:14 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:53

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Nutritional supplement' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:42:14 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:53

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '2000' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:42:14 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:53

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:42:14 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:53

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:42:14 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:53

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'once daily (QD)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:42:14 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:53

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:42:14 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:53

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:42:14 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:53

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:42:14 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:53

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'un UNK 2010' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:42:14 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:53

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:42:14 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:53

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:42:14 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:53

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:42:14 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:53

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:42:14 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:53

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 21 Aug 2020 18:42:14 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 21 Aug 2020 18:42:14 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 18:42:14 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:53

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: RESVERATROL - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 22 Aug 2020 05:21:26 |
| 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 Aug 2020 05:21:26 |
| Data point term sent to Coder | System | 21 Aug 2020 18:43:57 |
| User entered 'Resveratrol' | (b) (4), (b) (6) | 21 Aug 2020 18:43:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:53

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:43:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:53

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Nutritional supplement' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:43:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:53

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '500' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:43:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:53

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:43:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:53

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:43:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:53

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'once daily (QD)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:43:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:53

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:43:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:53

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:43:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:53

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:43:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'un Apr 2020' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:43:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:53

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:43:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:53

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:43:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:53

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:43:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:53

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:43:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:53

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 21 Aug 2020 18:43:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 21 Aug 2020 18:43:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 18:43:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:53

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANABOLIC AGENTS FOR SYSTEMIC USE, ATC: ANABOLIC STEROIDS, ATC: ANDROSTAN DERIVATIVES, PRODUCT: PRASTERONE, PRODUCTSYNONYM: DHEA - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 23 Aug 2020 20:04:39 |
| 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 Aug 2020 20:04:39 |
| Data point term sent to Coder | System | 21 Aug 2020 18:45:05 |
| User entered 'Dehydroepiandrosterone (DHEA) supplement' | (b) (4), (b) (6) | 21 Aug 2020 18:44:53 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:53

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:44:53 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:53

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Nutritional supplement' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:44:53 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:53

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '50' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:44:53 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:53

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:44:53 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:53

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:44:53 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:53

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'once daily (QD)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:44:53 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:53

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:44:53 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:53

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:44:53 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:53

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:44:53 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'un Apr 2020' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:44:53 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:53

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:44:53 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:53

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:44:53 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:53

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:44:53 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:53

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:44:53 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:53

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 21 Aug 2020 18:44:53 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 21 Aug 2020 18:44:53 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 18:44:53 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:53

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CRATAEGUS SPP. EXTRACT, PRODUCTSYNONYM: HAWTHORN BERRY - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 08 Sep 2020 13:12:57 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 08 Sep 2020 13:12:57 |
| Data point term sent to Coder | System | 21 Aug 2020 18:46:09 |
| User entered 'Hawthorn berry' | (b) (4), (b) (6) | 21 Aug 2020 18:46:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:53

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:53

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Nutritional supplement' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:53

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:53

[Dose unit](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'tablet (TABLET)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:53

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:53

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'once daily (QD)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:53

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:53

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:53

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'un Apr 2020' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:53

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:53

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:53

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:53

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:53

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 21 Aug 2020 18:46:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 21 Aug 2020 18:46:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 18:46:03 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:53

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 21 Aug 2020 18:48:24 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 21 Aug 2020 18:48:24 |
| Data point term sent to Coder | System | 21 Aug 2020 18:47:12 |
| User entered 'Zinc' | (b) (4), (b) (6) | 21 Aug 2020 18:46:40 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:53

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:40 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:53

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Nutritional supplement' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:40 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:53

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM). | (b) (4), (b) (6) | 07 Oct 2020 09:55:20 |
| Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated' (Site from DM). | Dawn Killian (b) (4) | 22 Sep 2020 00:30:35 |
| User entered '50' reason for change: Data Entry Error | Dawn Killian (b) (4) | 22 Sep 2020 00:30:28 |
| 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) | 18 Sep 2020 11:52:54 |
| User entered '5m' | (b) (4), (b) (6) | 21 Aug 2020 18:46:40 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:53

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:40 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:53

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:40 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:53

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'once daily (QD)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:40 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:53

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:40 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:53

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:40 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:53

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:40 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'un Apr 2020' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:40 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:53

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:40 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:53

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:40 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:53

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:40 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:53

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:46:40 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:53

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 21 Aug 2020 18:46:40 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 21 Aug 2020 18:46:40 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 18:46:40 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:53

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 21 Aug 2020 18:49:25 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 21 Aug 2020 18:49:25 |
| Data point term sent to Coder | System | 21 Aug 2020 18:48:13 |
| User entered 'Losartan' | (b) (4), (b) (6) | 21 Aug 2020 18:47:26 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:53

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:47:26 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:53

[Indication](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. (Site from DM). | (b) (4), (b) (6) | 07 Oct 2020 09:55:36 |
| Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'updated' (Site from DM). | Dawn Killian (b) (4) | 22 Sep 2020 00:31:56 |
| User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. (Site from DM). | (b) (4), (b) (6) | 18 Sep 2020 11:52:01 |
| User entered 'Hypertension' | (b) (4), (b) (6) | 21 Aug 2020 18:47:26 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:53

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '12.5' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:47:26 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:53

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:47:26 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:53

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:47:26 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:53

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'once daily (QD)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:47:26 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:53

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:47:26 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:53

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:47:26 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:53

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:47:26 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:53

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'un May 2016' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:47:26 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:53

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:47:26 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:53

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:47:26 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:53

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:47:26 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:53

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:47:26 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:53

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 21 Aug 2020 18:47:26 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 21 Aug 2020 18:47:26 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 18:47:26 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:53

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| 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. | (b) (4) Coder Import (b) (4) | 21 Aug 2020 18:51:12 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 21 Aug 2020 18:51:12 |
| Data point term sent to Coder | System | 21 Aug 2020 18:49:16 |
| User entered 'Carvedilol' | (b) (4), (b) (6) | 21 Aug 2020 18:48:32 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:53

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:48:32 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:53

[Indication](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. (Site from DM). | (b) (4), (b) (6) | 07 Oct 2020 09:55:48 |
| Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'updated' (Site from DM). | Dawn Killian (b) (4) | 22 Sep 2020 00:31:34 |
| User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. (Site from DM). | (b) (4), (b) (6) | 18 Sep 2020 11:51:41 |
| User entered 'Hypertension' | (b) (4), (b) (6) | 21 Aug 2020 18:48:32 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:53

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '3.125' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:48:32 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:53

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:48:32 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:53

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:48:32 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:53

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'once daily (QD)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:48:32 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:53

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:48:32 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:53

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:48:32 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:53

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:48:32 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'un May 2016' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:48:32 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:53

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:48:32 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:53

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:48:32 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:53

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:48:32 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:53

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:48:32 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:53

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 21 Aug 2020 18:48:32 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 21 Aug 2020 18:48:32 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 18:48:32 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:53

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| 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. | (b) (4) Coder Import (b) (4) | 21 Aug 2020 18:51:29 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 21 Aug 2020 18:51:29 |
| Data point term sent to Coder | System | 21 Aug 2020 18:50:23 |
| User entered 'Atorvastatin' | (b) (4), (b) (6) | 21 Aug 2020 18:49:27 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:53

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:49:27 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:53

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Hyperlipidemia' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:49:27 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:53

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '80' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:49:27 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:53

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:49:27 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:53

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:49:27 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:53

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'once daily (QD)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:49:27 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:53

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:49:27 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:53

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:49:27 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:53

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:49:27 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:53

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'un May 2016' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:49:27 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:53

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:49:27 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:53

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:49:27 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:53

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:49:27 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:53

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:49:27 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:53

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 21 Aug 2020 18:49:27 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 21 Aug 2020 18:49:27 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 18:49:27 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:53

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| 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: ASA - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 25 Sep 2020 12:32:44 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 25 Sep 2020 12:32:44 |
| 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 - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 17 Sep 2020 21:59:44 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 17 Sep 2020 21:59:44 |
| 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 - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 23:28:24 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 23:28:24 |
| Data point term sent to Coder | System | 21 Aug 2020 18:51:28 |
| User entered 'Acetylsalicylic acid (ASA)' | (b) (4), (b) (6) | 21 Aug 2020 18:51:23 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:53

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:51:23 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:53

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Cardiac prophylaxis' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:51:23 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:53

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '81' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:51:23 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:53

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:51:23 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:53

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:51:23 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:53

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'once daily (QD)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:51:23 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:53

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:51:23 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:53

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:51:23 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:53

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:51:23 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:53

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'un UNK 1990' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:51:23 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:53

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:51:23 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:53

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:51:23 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:53

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:51:23 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:53

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:51:23 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:53

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 21 Aug 2020 18:51:23 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 21 Aug 2020 18:51:23 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 18:51:23 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:53

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: PRASUGREL - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 22 Aug 2020 05:45:29 |
| 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 Aug 2020 05:45:29 |
| Data point term sent to Coder | System | 21 Aug 2020 18:53:31 |
| User entered 'Prasugrel' | (b) (4), (b) (6) | 21 Aug 2020 18:52:43 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:53

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:52:43 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:53

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Clotting prophylaxis' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:52:43 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:53

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '10' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:52:43 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:53

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:52:43 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:53

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:52:43 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:53

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'once daily (QD)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:52:43 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:53

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:52:43 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:53

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:52:43 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:53

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:52:43 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:53

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'un May 2016' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:52:43 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:53

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:52:43 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:53

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:52:43 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:53

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:52:43 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:53

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 18:52:43 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:53

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 21 Aug 2020 18:52:43 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 21 Aug 2020 18:52:43 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 18:52:43 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:27:53

Name of Medication

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:13:45 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| 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) | 17 Nov 2020 07:14:04 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 17 Nov 2020 07:14:04 |
| Data point term sent to Coder | System | 16 Nov 2020 22:22:42 |
| User entered 'Influenza vaccine' | (b) (4), (b) (6) | 16 Nov 2020 22:21:42 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:27:53

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:13:45 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 16 Nov 2020 22:21:42 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:27:53

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:13:45 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'flu pervetion' | (b) (4) (b) (4), (b) (6) | 16 Nov 2020 22:21:42 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:27:53

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:13:45 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '0.5' | (b) (4), (b) (6) | 16 Nov 2020 22:21:42 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:27:53

[Dose unit](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:13:45 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM). | (b) (4), (b) (6) | 02 Apr 2021 10:17:09 |
| Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' answered with 'updateed' (Site from DM). | Dawn Killian (b) (4) | 26 Mar 2021 21:09:07 |
| User entered 'mL (mL)' reason for change: Data Entry Error | Dawn Killian (b) (4) | 26 Mar 2021 21:09:03 |
| User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM). | (b) (4), (b) (6) | 29 Jan 2021 17:13:34 |
| User entered 'mg (mg)' | | 16 Nov 2020 22:21:42 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:27:53

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:13:45 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Nov 2020 22:21:42 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:27:53

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:13:45 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'once (ONCE)' | (b) (4) (b) (4), (b) (6) | 16 Nov 2020 22:21:42 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:27:53

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:13:45 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Nov 2020 22:21:42 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:27:53

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:13:45 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4), (b) (6) | 16 Nov 2020 22:21:42 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:27:53

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:13:45 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Nov 2020 22:21:42 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:27:53

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:13:45 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '21 Oct 2020' | (b) (4) (b) (4), (b) (6) | 16 Nov 2020 22:21:42 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:27:53

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:13:45 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 16 Nov 2020 22:21:42 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:27:53

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:13:45 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 16 Nov 2020 22:21:42 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:27:53

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:13:45 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered '21 Oct 2020' | (b) (4) (b) (4), (b) (6) | 16 Nov 2020 22:21:42 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:27:53

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:13:45 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:19:35 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 16 Nov 2020 22:21:42 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:27:53

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:13:45 |
| User entered empty. | System | 16 Nov 2020 22:21:42 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:13:45 |
| User entered empty. | System | 16 Nov 2020 22:21:42 |

US3292245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:27:53

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:13:45 |
| User entered empty. | System | 16 Nov 2020 22:21:42 |

US3292245

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:27:53

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 21:18:16 |
| User entered 'No (N)' | (b) (4) Dawn Killian (b) (4) (b) (4) | 04 Feb 2021 16:47:35 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:12 |
| User entered 'USA-US072-2021-MRNA-1273-P301000021' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:21 |
| User entered 'Yes (Y)' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:21 |
| User entered 'No (N)' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:21 |
| User entered 'No (N)' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:21 |
| User entered 'No (N)' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:21 |
| User entered 'No (N)' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:21 |
| User entered 'No (N)' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:21 |
| User entered 'Yes (Y)' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:21 |
| User entered 'Douglas' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:21 |
| User entered 'Denham' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

Site Address: [Street](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:21 |
| User entered '7940 Floyd Curl Drive' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:21 |
| User entered 'San Antonio' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:21 |
| User entered '78229' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| User entered 'US' | (b) (4) System | 29 Apr 2021 13:36:48 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 29 Apr 2021 13:36:48 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:12 |
| User entered 'USA-US072-2021-MRNA-1273-P301000021' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:21 |
| User entered 'Yes (Y)' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:21 |
| User entered 'No (N)' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:21 |
| User entered 'No (N)' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:21 |
| User entered 'No (N)' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:21 |
| User entered 'No (N)' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:21 |
| User entered 'No (N)' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:21 |
| User entered 'Yes (Y)' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:21 |
| User entered 'Douglas' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:21 |
| User entered 'Denham' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:21 |
| User entered '7940 Floyd Curl Drive' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:21 |
| User entered 'San Antonio' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:33:21 |
| User entered '78229' | System | 29 Apr 2021 13:31:15 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| User entered 'US' | (b) (4) System | 29 Apr 2021 13:36:48 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 29 Apr 2021 13:36:48 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:27:53

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| User entered '29/Apr/2021 09:36' | (b) (4) System | 29 Apr 2021 13:36:48 |

US3292245

Folder: SAE USA-US072-2021-MRNA-1273-P301000021

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:27:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 29 Apr 2021 17:56:43 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:36:48 |