

US3292236 (Prod: Clinical Trials of Texas, Inc)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:56:29

All time stamps listed in this document are displayed in GMT

US3292236

Form: Participant Creation

Generated On: 26 Nov 2020 10:56:29

[Participant ID](#)

US3292236

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

US3292236

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:56:29

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

Generated On: 26 Nov 2020 10:56:29

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1940 |
| Age | 80 |
| Age Units | YEARS |
| Age (Derived) | 80 |
| Sex | Female <input checked="" type="radio"/> Male <input type="radio"/> |
| Ethnicity | Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/> |
| Race (Check All That Apply) | |
| White | True |
| Black | False |
| Asian | False |
| American Indian or Alaska Native | False |
| Native Hawaiian or other Pacific Islander | False |
| Other | False |
| If race is Other, specify _____ | |
| Unknown | False |
| Not reported | False |

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:29

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

Generated On: 26 Nov 2020 10:56:29

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:56:29

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:29

| | |
|---|--|
| Condition | SEASONAL ALLERGIES |
| Start date (dd MMM yyyy) | UN UNK 1972 |
| 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 1972 |
| Start Year (derived) | 1972 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:29

| | |
|---|--|
| Condition | ALLERGIES TO SOY |
| Start date (dd MMM yyyy) | UN UNK 1987 |
| 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 1987 |
| Start Year (derived) | 1987 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:29

| | |
|---|--|
| Condition | HYSTERECTOMY |
| Start date (dd MMM yyyy) | UN UNK 1979 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 1979 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1979 |
| Start Year (derived) | 1979 |
| Stop Month and Year (derived) | JAN 1979 |
| Stop Year (derived) | 1979 |

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:29

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

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:29

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

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:29

| | |
|---|--|
| Condition | CATARACT REMOVAL OU - BILATERAL |
| Start date (dd MMM yyyy) | UN UNK 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 UNK 2016 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2016 |
| Start Year (derived) | 2016 |
| Stop Month and Year (derived) | JAN 2016 |
| Stop Year (derived) | 2016 |

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:29

| | |
|---|--|
| Condition | UPPER GI BLEED |
| Start date (dd MMM yyyy) | UN UNK 1986 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 1986 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1986 |
| Start Year (derived) | 1986 |
| Stop Month and Year (derived) | JAN 1986 |
| Stop Year (derived) | 1986 |

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:29

| | |
|---|--|
| Condition | BILATERAL HEARING LOSS |
| 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 (9)

Generated On: 26 Nov 2020 10:56:29

| | |
|---|--|
| Condition | CATARACTS OU |
| Start date (dd MMM yyyy) | UN UNK 1986 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2016 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1986 |
| Start Year (derived) | 1986 |
| Stop Month and Year (derived) | JAN 2016 |
| Stop Year (derived) | 2016 |

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:29

| | |
|---|--|
| Condition | STOMACH ULCER |
| Start date (dd MMM yyyy) | UN UNK 1986 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 1986 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1986 |
| Start Year (derived) | 1986 |
| Stop Month and Year (derived) | JAN 1986 |
| Stop Year (derived) | 1986 |

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:29

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

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:29

| | |
|---|--|
| Condition | SQUAMOUS CELL CANCER - RLE |
| Start date (dd MMM yyyy) | UN UNK 2000 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2000 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2000 |
| Start Year (derived) | 2000 |
| Stop Month and Year (derived) | JAN 2000 |
| Stop Year (derived) | 2000 |

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:29

| | |
|---|--|
| Condition | OSTEOPENIA |
| Start date (dd MMM yyyy) | UN UNK 2000 |
| 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 2000 |
| Start Year (derived) | 2000 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:29

| | |
|---|--|
| Condition | MIGRAINE HEADACHES |
| Start date (dd MMM yyyy) | UN UNK 1987 |
| 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 1987 |
| Start Year (derived) | 1987 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:56:29

| | |
|---|--|
| Condition | UTERINE FIBROIDS |
| Start date (dd MMM yyyy) | UN UNK 1979 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 1979 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1979 |
| Start Year (derived) | 1979 |
| Stop Month and Year (derived) | JAN 1979 |
| Stop Year (derived) | 1979 |

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

| | |
|---|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 20 AUG 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 08:36 (24 HR) |
| Vital Signs Date and Time (derived) | 20 AUG 2020 08:36 |
| Height (<i>xxx.x</i>) | 171.0 cm |
| Weight (<i>xxx.x</i>) | 59.7 kg |
| BMI (<i>xxx.x</i>) | 20.41654 kg/m ² |
| BMI units | KG/M2 |
| Temperature (<i>xxx.x</i>) | ND - Not Done |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | ND - Not Done |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | ND - Not Done |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | ND - Not Done |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | ND - Not Done |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:29

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: Childbearing Potential

Generated On: 26 Nov 2020 10:56:29

| | |
|--|---|
| Date of assessment (<i>dd MMM yyyy</i>) | 20 AUG 2020 |
| Is the participant of childbearing potential? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| If No, what is the reason? | Surgically sterile <input checked="" type="radio"/> |
| | Post-menopausal <input type="radio"/> |
| | Partner medically sterile <input type="radio"/> |
| | Not reached age of Menarche <input type="radio"/> |
| | Other <input type="radio"/> |
| If Partner medically sterile or Other, specify | |
| If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>) | UN UNK 1979 |
| Date of surgery unknown | False |
| If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>) | |
| Date of last menstruation unknown | False |

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:29

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:29

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

Generated On: 26 Nov 2020 10:56:29

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

Generated On: 26 Nov 2020 10:56:29

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

What was the participant's randomization number? 187235

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

Generated On: 26 Nov 2020 10:56:29

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

| | |
|-------------------------------------|--|
| 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) | 09:14 (24 HR) |
| Vital Signs Date and Time (derived) | 20 AUG 2020 09:14 |
| Temperature (xxx.x) | 36.8 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 72 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) | 59 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 20 AUG 2020 |
| Time of assessment (00:00-23:59) | 10:47 (24 HR) |
| Vital Signs Date and Time (derived) | 20 AUG 2020 10:47 |
| Temperature (xxx.x) | 36.4 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 62 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 20 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 114 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 60 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:29

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

Generated On: 26 Nov 2020 10:56:29

| | |
|--|--|
| Was study treatment given? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| If No, reason not given | Participant declined due to Adverse Event <input type="radio"/> |
| | Physician withheld dose due to Adverse Event <input type="radio"/> |
| | Death <input type="radio"/> |
| | Lost To Follow-Up <input type="radio"/> |
| | Physician Decision <input type="radio"/> |
| | Pregnancy <input type="radio"/> |
| | Protocol Deviation <input type="radio"/> |
| | Study Terminated by Sponsor <input type="radio"/> |
| | Withdrawal of Consent by Participant <input type="radio"/> |
| | Confirmed COVID-19 <input type="radio"/> |
| | Other <input type="radio"/> |
| 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) | 10:14 (24 HR) |
| Treatment Date and Time (derived) | 20 AUG 2020 10:14 |
| Which arm was used to give treatment? | Left Arm <input checked="" type="radio"/> |
| | Right Arm <input type="radio"/> |
| 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

Generated On: 26 Nov 2020 10:56:29

| | |
|--|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (<i>dd MMM yyyy</i>) | 20 AUG 2020 |
| Collection time (<i>00:00-23:59</i>) | 09:37 (24 HR) |
| Collection date and time (derived) | 20 AUG 2020 09:37 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:56:29

| | | | |
|--|---------------------------|--|------------------------------------|
| Collection date (<i>dd MMM yyyy</i>) | | | 20 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (<i>00:00 - 23:59</i>) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 09:27 | 20 AUG 2020 09:27 |
| Nasopharyngeal Swab 2 | No | | |

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

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: 26 Nov 2020 10:56:29

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

20 AUG 2020 10:59

PC Open Date & Time

20 AUG 2020 10:34

PC Close Date & Time

20 AUG 2020 13:04

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.3 °F

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 20 AUG 2020 18:27 |
| PC Open Date & Time | 20 AUG 2020 13:59 |
| PC Close Date & Time | 21 AUG 2020 11:59 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °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

21 AUG 2020 15:04

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 18:02

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:29

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

97.0 °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

23 AUG 2020 18:05

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 19:29

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

25 AUG 2020 17:26

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

26 AUG 2020 18:19

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

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 11:00

PC Open Date & Time

20 AUG 2020 10:34

PC Close Date & Time

20 AUG 2020 13:04

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

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 18:28

PC Open Date & Time

20 AUG 2020 13:59

PC Close Date & Time

21 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:29

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 15:03

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:29

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 18:03

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:29

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 18:06

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:29

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 19:29

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 17:26

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:29

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 18:20

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 20 AUG 2020 11:01 |
| PC Open Date & Time | 20 AUG 2020 10:34 |
| PC Close Date & Time | 20 AUG 2020 13:04 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 20 AUG 2020 18:30 |
| PC Open Date & Time | 20 AUG 2020 13:59 |
| PC Close Date & Time | 21 AUG 2020 11:59 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

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 ☒

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 21 AUG 2020 15:05 |
| PC Open Date & Time | 21 AUG 2020 12:00 |
| PC Close Date & Time | 22 AUG 2020 11:59 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

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 ☒

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 22 AUG 2020 18:04 |
| PC Open Date & Time | 22 AUG 2020 12:00 |
| PC Close Date & Time | 23 AUG 2020 11:59 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

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 ☒

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 23 AUG 2020 18:06 |
| PC Open Date & Time | 23 AUG 2020 12:00 |
| PC Close Date & Time | 24 AUG 2020 11:59 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

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 ☒

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 24 AUG 2020 19:30 |
| PC Open Date & Time | 24 AUG 2020 12:00 |
| PC Close Date & Time | 25 AUG 2020 11:59 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

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 ☒

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 25 AUG 2020 17:27 |
| PC Open Date & Time | 25 AUG 2020 12:00 |
| PC Close Date & Time | 26 AUG 2020 11:59 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

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 ☒

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 26 AUG 2020 18:21 |
| PC Open Date & Time | 26 AUG 2020 12:00 |
| PC Close Date & Time | 27 AUG 2020 11:59 |

US3292236

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292236

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292236

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

PATIENT DID NOT ANSWER
CALL.

If Contact Not Made, please provide Comments

US3292236

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

| | |
|-------------------------------------|---|
| 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) | 09:32 (24 HR) |
| Vital Signs Date and Time (derived) | 17 SEP 2020 09:32 |
| Temperature (xxx.x) | 36.3 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) | 17 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 116 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 65 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

| | |
|-------------------------------------|--|
| Timepoint | Pre-Dose <input type="radio"/> |
| | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 17 SEP 2020 |
| Time of assessment (00:00-23:59) | 11:21 (24 HR) |
| Vital Signs Date and Time (derived) | 17 SEP 2020 11:21 |
| Temperature (xxx.x) | 36.8 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 64 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 20 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 121 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 65 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:29

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.

US3292236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:29

| | |
|--|--|
| Was study treatment given? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| If No, reason not given | Participant declined due to Adverse Event <input type="radio"/> |
| | Physician withheld dose due to Adverse Event <input type="radio"/> |
| | Death <input type="radio"/> |
| | Lost To Follow-Up <input type="radio"/> |
| | Physician Decision <input type="radio"/> |
| | Pregnancy <input type="radio"/> |
| | Protocol Deviation <input type="radio"/> |
| | Study Terminated by Sponsor <input type="radio"/> |
| | Withdrawal of Consent by Participant <input type="radio"/> |
| | Confirmed COVID-19 <input type="radio"/> |
| | Other <input type="radio"/> |
| If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify | |
| What was the study treatment? | MRNA-1273 OR PLACEBO |
| What was the treatment date? (dd MMM yyyy) | 17 SEP 2020 |
| What was the treatment time? (00:00-23:59) | 10:49 (24 HR) |
| Treatment Date and Time (derived) | 17 SEP 2020 10:49 |
| Which arm was used to give treatment? | Left Arm <input checked="" type="radio"/> |
| | Right Arm <input type="radio"/> |
| What was the frequency of the study treatment dosing? | ONCE |
| What was the route of administration for the study treatment? | INTRAMUSCULAR |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:29

| | |
|--|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (<i>dd MMM yyyy</i>) | 17 SEP 2020 |
| Collection time (<i>00:00-23:59</i>) | 09:42 (24 HR) |
| Collection date and time (derived) | 17 SEP 2020 09:42 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:56:29

| 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 | 10:00 | 17 SEP 2020 10:00 |
| Nasopharyngeal Swab 2 | No | | |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 11:26

PC Open Date & Time

17 SEP 2020 11:09

PC Close Date & Time

17 SEP 2020 13:39

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

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 94.4 °F

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 17 SEP 2020 15:44 |
| PC Open Date & Time | 17 SEP 2020 14:34 |
| PC Close Date & Time | 18 SEP 2020 11:59 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 16:20

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 21:03

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:29

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 18:54

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 17:20

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 17:34

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 06:17

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

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 11:26

PC Open Date & Time

17 SEP 2020 11:09

PC Close Date & Time

17 SEP 2020 13:39

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

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 15:45

PC Open Date & Time

17 SEP 2020 14:34

PC Close Date & Time

18 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:29

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 16:21

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 21:03

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:29

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 18:55

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:29

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 17:21

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:29

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 17:35

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:29

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

24 SEP 2020 06:17

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 17 SEP 2020 11:27 |
| PC Open Date & Time | 17 SEP 2020 11:09 |
| PC Close Date & Time | 17 SEP 2020 13:39 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 17 SEP 2020 15:46 |
| PC Open Date & Time | 17 SEP 2020 14:34 |
| PC Close Date & Time | 18 SEP 2020 11:59 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

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 ☒

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 18 SEP 2020 16:22 |
| PC Open Date & Time | 18 SEP 2020 12:00 |
| PC Close Date & Time | 19 SEP 2020 11:59 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

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 ☒

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 19 SEP 2020 21:04 |
| PC Open Date & Time | 19 SEP 2020 12:00 |
| PC Close Date & Time | 20 SEP 2020 11:59 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

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 ☒

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 20 SEP 2020 18:56 |
| PC Open Date & Time | 20 SEP 2020 12:00 |
| PC Close Date & Time | 21 SEP 2020 11:59 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

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 ☒

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 21 SEP 2020 17:21 |
| PC Open Date & Time | 21 SEP 2020 12:00 |
| PC Close Date & Time | 22 SEP 2020 11:59 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

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 ☒

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 22 SEP 2020 17:36 |
| PC Open Date & Time | 22 SEP 2020 12:00 |
| PC Close Date & Time | 23 SEP 2020 11:59 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

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 ☒

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 24 SEP 2020 06:18 |
| PC Open Date & Time | 23 SEP 2020 12:00 |
| PC Close Date & Time | 24 SEP 2020 11:59 |

US3292236

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292236

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292236

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

| | |
|---|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 15 OCT 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 11:00 (24 HR) |
| Vital Signs Date and Time (derived) | 15 OCT 2020 11:00 |
| Temperature (<i>xxx.x</i>) | 36.7 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | 74 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | 103 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | 59 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:29

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.

US3292236

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:29

| | |
|--|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (<i>dd MMM yyyy</i>) | 15 OCT 2020 |
| Collection time (<i>00:00-23:59</i>) | 11:10 (24 HR) |
| Collection date and time (derived) | 15 OCT 2020 11:10 |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 05:33:28

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

28 OCT 2020 09:18:59

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 10:40:58

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 12:58:31

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| TIMEPOINT | DAY 61 |
|---|--|
| Have 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"/> |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

[Patient Cloud Close Date & Time](#)

21 OCT 2020 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| TIMEPOINT | DAY 68 |
|---|--|
| Have 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"/> |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 28 OCT 2020 23:59 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| TIMEPOINT | DAY 75 |
|---|---|
| Have 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"/> |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

[Patient Cloud Close Date & Time](#)

04 NOV 2020 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| TIMEPOINT | DAY 82 |
|---|---|
| Have 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"/> |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

[Patient Cloud Close Date & Time](#)

11 NOV 2020 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| TIMEPOINT | DAY 89 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 18 NOV 2020 23:59 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 09:47:24

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 103

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

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

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

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

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

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

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2020 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| TIMEPOINT | DAY 117 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| TIMEPOINT | DAY 124 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| TIMEPOINT | DAY 131 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 30 DEC 2020 23:59 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 145

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

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

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

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

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

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

No ☐

Yes ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

[Patient Cloud Close Date & Time](#)

20 JAN 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

[Patient Cloud Close Date & Time](#)

10 FEB 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| 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 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"/> |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 17 FEB 2021 23:59 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

[Patient Cloud Close Date & Time](#)

24 FEB 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| TIMEPOINT | DAY 194 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| 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="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"/> |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| 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 <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"/> |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

[Patient Cloud Close Date & Time](#)

24 MAR 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 222

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

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| 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="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"/> |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| TIMEPOINT | DAY 236 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

[Patient Cloud Close Date & Time](#)

14 APR 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 243

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

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 250

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

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| 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="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"/> |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 271

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

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| 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"/> |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| 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="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"/> |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| 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="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"/> |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 404

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

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

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

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

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

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

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☐
Yes ☐

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| 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="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"/> |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| 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="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"/> |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| 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="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"/> |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☐
Yes ☐

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 488

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

No ☐
Yes ☐

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

No ☐
Yes ☐

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

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

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

No ☐
Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

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

No ☐
Yes ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☐
Yes ☐

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

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

No ☐

Yes ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

26 FEB 2022 00:01

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02 MAR 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| 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="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"/> |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| 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="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"/> |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 635

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

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

No ☐

Yes ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| 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="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"/> |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| TIMEPOINT | DAY 691 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

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13 JUL 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| TIMEPOINT | DAY 698 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

Date and time of submission

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US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

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Generated On: 26 Nov 2020 10:56:29

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

Date and time of submission

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US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| 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"/> |

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

Date and time of submission

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US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

Date and time of submission

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06 AUG 2022 00:01

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10 AUG 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

| 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"/> |

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

Date and time of submission

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

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Folder: New Safety Follow Up Diary (1)

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

Date and time of submission

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20 AUG 2022 00:01

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24 AUG 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

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

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27 AUG 2022 00:01

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31 AUG 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 747

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

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

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

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

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

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

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

Date and time of submission

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07 SEP 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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14 SEP 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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21 SEP 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3292236

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:56:29

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3292236

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:56:29

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

| | |
|--|--|
| AEID | USA-US072-2020-MRNA-1273-P30 1000001 |
| Adverse event | FIBROMUSCULAR DYSPLASIA |
| 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) | 4 SEP 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 5 SEP 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 4 SEP 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 5 SEP 2020 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |
| v6.020 DTW (1102) | 346 of 1954 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

THIS REPORT IS FOLLOWING
PATIENT'S INITIAL REPORT TO
STAFF ON THE MORNING OF
09SEP2020. PT RECEIVED FIRST
IP INJECTION ON 20AUG2020.

ON 21ST, PT HAD
APPOINTMENT WITH DOCTOR
FOR MIGRAINES. DOCTOR
PRESCRIBED AIMOVIG, WHICH
PT STARTED IMMEDIATELY.

ON 03SEP, PT WAS "NOT
FEELING NORMAL". SHE
COULD NOT DESCRIBE HER
SYMPTOMS, SIMPLY STATING
SHE WAS NOT FEELING
NORMAL. ON 04SEP PT STATES
SHE WOKE UP TO THE ROOM
SPINNING, SHE WAS
EXPERIENCING NAUSEA, AND
CALLED AN AMBULANCE.

WHILE IN THE AMBULANCE,
EMT GAVE PT SOMETHING FOR
NAUSEA, THOUGH PT CANNOT
RECALL WHAT IT WAS. WHILE

IN THE ER, PT STATES
DOCTORS DID "EVERY TEST
KNOWN TO MAN", BUT COULD
NOT FIND ANYTHING
ABNORMAL. DOCTORS

DECIDED TO CONDUCT MRI
WITH CONTRAST. ACCORDING
TO PATIENT, SHE WAS TOLD
BY HER DOCTOR THAT SHE

HAD "POSSIBLE
FIBROMUSCULAR DYSPLASIA".
AT THIS TIME, PT WAS UNABLE
TO PROVIDE ANY FURTHER

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

INFORMATION. WE WILL
REQUEST MEDICAL RECORDS
FROM HOSPITAL ASAP.
UPDATE: DISCHARGE
SUMMARY SENT TO SAFETY
24SEP2020. STATES "MRI
FINDINGS OF BEADING IN
DISTAL CERVICAL ARTERIES
SUGGESTED POSSIBLE
FIBROMUSCULAR DYSPLASIA."
D/C SUMMARY ALSO STATES
THAT PATIENT IS TO FOLLOW
UP WITH NEUROLOGIST TO
DISCUSS THESE FINDINGS. NO
FURTHER INFORMATION OR
LAB RESULTS GIVEN. COVID
TESTING NOT MENTIONED.
PLEASE REVIEW REPORT.

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

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

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

v6.020 DTW (1102)

350 of 1954

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:56:29

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

Yes ☒

No ☐

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

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:29

| | |
|--------------------------------|--|
| Name of Medication | CALCIUM |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | OSTEOPENIA |
| Dose per administration | 1800 |
| Dose unit | mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/> |
| If dose unit is Other, specify | |
| Frequency | once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/> |
| If frequency is Other, specify | |
| Route of administration | Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/> |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:29

| | |
|--------------------------------------|--|
| Name of Medication | MAGNESIUM |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | NUTRITIONAL SUPPLEMENT |
| Dose per administration | 500 |
| Dose unit | mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/> |
| If dose unit is Other, specify _____ | |
| Frequency | once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/> |
| If frequency is Other, specify _____ | |
| Route of administration | Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/> |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:29

| | | |
|---|--------------------------|----------------------------------|
| | 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"/> |
| <hr/> | | |
| If route of administration is Other, specify <input type="text"/> | | |
| <hr/> | | |
| Start date (dd MMM yyyy) | UN | UNK 2015 |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| <hr/> | | |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/> | | |
| <hr/> | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| <hr/> | | |
| 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"/> |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:29

| | |
|--------------------------------------|--|
| Name of Medication | POTASSIUM |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | NUTRITIONAL SUPPLEMENT |
| Dose per administration | 198 |
| Dose unit | mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/> |
| If dose unit is Other, specify _____ | |
| Frequency | once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/> |
| If frequency is Other, specify _____ | |
| Route of administration | Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/> |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:29

| | |
|--------------------------------------|--|
| Name of Medication | COENZYME Q10 |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | NUTRITIONAL SUPPLEMENT |
| Dose per administration | 100 |
| Dose unit | mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/> |
| If dose unit is Other, specify _____ | |
| Frequency | once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/> |
| If frequency is Other, specify _____ | |
| Route of administration | Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/> |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:29

| | | |
|---|--------------------------|----------------------------------|
| | 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"/> |
| <hr/> | | |
| If route of administration is Other, specify <input type="text"/> | | |
| <hr/> | | |
| Start date (dd MMM yyyy) | UN | UNK 2017 |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| <hr/> | | |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/> | | |
| <hr/> | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| <hr/> | | |
| 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"/> |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:29

| | |
|--------------------------------------|--|
| Name of Medication | TURMERIC |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | NUTRITIONAL SUPPLEMENT |
| Dose per administration | 500 |
| Dose unit | mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/> |
| If dose unit is Other, specify _____ | |
| Frequency | once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/> |
| If frequency is Other, specify _____ | |
| Route of administration | Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/> |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:29

| | | |
|---|--------------------------|----------------------------------|
| | 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"/> |
| <hr/> | | |
| If route of administration is Other, specify <input type="text"/> | | |
| <hr/> | | |
| Start date (dd MMM yyyy) | UN | UNK 2015 |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| <hr/> | | |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/> | | |
| <hr/> | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| <hr/> | | |
| 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"/> |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:29

| | |
|--------------------------------|--|
| Name of Medication | SUMATRIPTAN |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | MIGRAINE HEADACHES |
| Dose per administration | 100 |
| Dose unit | mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/> |
| If dose unit is Other, specify | |
| Frequency | once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/> |
| If frequency is Other, specify | |
| Route of administration | Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/> |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:29

| | | |
|--|--------------------------|----------------------------------|
| | 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 1985 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:29

| | |
|--------------------------------------|--|
| Name of Medication | FISH OIL |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | HYPERLIPIDEMIA |
| Dose per administration | 100 |
| Dose unit | mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/> |
| If dose unit is Other, specify _____ | |
| Frequency | once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/> |
| If frequency is Other, specify _____ | |
| Route of administration | Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/> |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:29

| | |
|--------------------------------|--|
| Name of Medication | AIMOVIG |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | MIGRAINE HEADACHES |
| Dose per administration | 70 |
| Dose unit | mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/> |
| If dose unit is Other, specify | |
| Frequency | once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/> |
| If frequency is Other, specify | |
| Route of administration | Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input checked="" type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/> |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:29

| | |
|--------------------------------------|--|
| Name of Medication | MECLIZINE |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | VERTIGO |
| Dose per administration | 25 |
| Dose unit | mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/> |
| If dose unit is Other, specify _____ | |
| Frequency | once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input checked="" type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/> |
| If frequency is Other, specify _____ | |
| Route of administration | Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/> |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:29

| | | |
|---|--------------------------|----------------------------------|
| | 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"/> |
| <hr/> | | |
| If route of administration is Other, specify <input type="text"/> | | |
| <hr/> | | |
| Start date (dd MMM yyyy) | | 05 SEP 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| <hr/> | | |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/> | | |
| <hr/> | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| <hr/> | | |
| Separate Dosage Number (derived) | | 3 |
| Interval Dosage Unit Number (derived) | | 1 |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3292236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:56:29

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3292236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 10:56:29

| Procedure/Surgery date (<i>dd MMM yyyy</i>) | Procedure/Surgery | Indication | If indication is Other, specify |
|---|-------------------|------------|---------------------------------|
| 4 SEP 2020 | BRAIN MRI | Diagnostic | |
| 4 SEP 2020 | BRAIN MRA | Diagnostic | |

US3292236

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:56:29

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

US3292236

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:56:29

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 ☐

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

| | |
|--|--|
| SAEID | USA-US072-2020-MRNA-1273-P301000001 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | DOUGLAS |
| Investigator's Last Name | DENHAM |
| Site Address: Street | 7940 FLOYD CURL DRIVE |
| Site Address: City | SAN ANTONIO |
| Site Address: State | |
| Site Address: Postal Code | 78229 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 6 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:56:29

| | |
|---|---|
| SAEID | USA-US072-2020-MRNA-1273-P301000001 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | DOUGLAS |
| Investigator's Last Name | DENHAM |
| Site Address: Street | 7940 FLOYD CURL DRIVE |
| Site Address: City | SAN ANTONIO |
| Site Address: State | |
| Site Address: Postal Code | 78229 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 6 |
| Date of submission (Pre-filled from custom function) | 10/SEP/2020 13:31 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:56:29

| | |
|---|--|
| SAEID | USA-US072-2020-MRNA-1273-P301000001 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | DOUGLAS |
| Investigator's Last Name | DENHAM |
| Site Address: Street | 7940 FLOYD CURL DRIVE |
| Site Address: City | SAN ANTONIO |
| Site Address: State | |
| Site Address: Postal Code | 78229 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 6 |
| Date of submission (Pre-filled from custom function) | 22/SEP/2020 10:49 |
| 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 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:56:29

| | |
|---|--|
| SAEID | USA-US072-2020-MRNA-1273-P301000001 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | DOUGLAS |
| Investigator's Last Name | DENHAM |
| Site Address: Street | 7940 FLOYD CURL DRIVE |
| Site Address: City | SAN ANTONIO |
| Site Address: State | |
| Site Address: Postal Code | 78229 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 6 |
| Date of submission (Pre-filled from custom function) | 25/SEP/2020 16:49 |
| 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 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:56:29

| | |
|---|---|
| SAEID | USA-US072-2020-MRNA-1273-P301000001 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | DOUGLAS |
| Investigator's Last Name | DENHAM |
| Site Address: Street | 7940 FLOYD CURL DRIVE |
| Site Address: City | SAN ANTONIO |
| Site Address: State | |
| Site Address: Postal Code | 78229 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 6 |
| Date of submission (Pre-filled from custom function) | 14/OCT/2020 13:36 |
| 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 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 10:56:29

| | |
|---|--|
| SAEID | USA-US072-2020-MRNA-1273-P301000001 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | DOUGLAS |
| Investigator's Last Name | DENHAM |
| Site Address: Street | 7940 FLOYD CURL DRIVE |
| Site Address: City | SAN ANTONIO |
| Site Address: State | |
| Site Address: Postal Code | 78229 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 6 |
| Date of submission (Pre-filled from custom function) | 05/NOV/2020 15:03 |
| 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 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 10:56:29

| | |
|---|--|
| SAEID | USA-US072-2020-MRNA-1273-P301000001 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | DOUGLAS |
| Investigator's Last Name | DENHAM |
| Site Address: Street | 7940 FLOYD CURL DRIVE |
| Site Address: City | SAN ANTONIO |
| Site Address: State | |
| Site Address: Postal Code | 78229 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 6 |
| Date of submission (Pre-filled from custom function) | 06/NOV/2020 14:31 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

Audit

US3292236 (Prod: Clinical Trials of Texas, Inc)

US3292236

Form: Participant Creation

Generated On: 26 Nov 2020 10:56:29

[Participant ID](#)

| Audit | User | Time (GMT) |
|--------------------------|---|----------------------|
| User entered 'US3292236' | RWS_ENDPOINT ENDPOINT (b) (4) <div></div> | 20 Aug 2020 13:54:53 |

US3292236

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:56:29

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:44:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 13:20:03 |

US3292236

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:44:08 |
| User entered '20 AUG 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 13:54:54 |

US3292236

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:44:08 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 21 Aug 2020 13:20:03 |

US3292236

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:56:29

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'SCRN' | System | 21 Aug 2020 13:20:03 |

US3292236

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:29

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:44:27 |
| User entered (b) (6) 1940' | RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 13:54:55 |

US3292236

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:29

[Age](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:44:27 |
| User entered '80' | (b) (4), (b) (6) | 21 Aug 2020 13:20:30 |

US3292236

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:29

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| User entered 'YEARS' | System | 21 Aug 2020 13:20:30 |

US3292236

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:29

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '80' | System | 20 Aug 2020 15:25:14 |

US3292236

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:29

[Sex](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:44:27 |
| User entered 'Female (F)' reason for change: Data Entry Error | Victoria Hernandez (b) (4) | 21 Sep 2020 22:06:57 |
| User entered 'Male (M)' | (b) (4), (b) (6) | 21 Aug 2020 13:20:30 |

US3292236

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:29

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:44:27 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4), (b) (6) | 21 Aug 2020 13:20:30 |

US3292236

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:29

[White](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:44:27 |
| User entered '1' | (b) (4), (b) (6) | 21 Aug 2020 13:20:30 |

US3292236

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:29

[Black](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:44:27 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:20:30 |

US3292236

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:29

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:44:27 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:20:30 |

US3292236

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:29

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:44:27 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:20:30 |

US3292236

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:29

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:44:27 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:20:30 |

US3292236

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:29

[Other](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:44:27 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:20:30 |

US3292236

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:29

If race is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:44:27 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:20:30 |

US3292236

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:29

[Unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:44:27 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:20:30 |

US3292236

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:29

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:44:27 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:20:30 |

US3292236

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:29

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:44:53 |
| User entered '20 Aug 2020' | Nathan Cortez (b) (4) | 20 Aug 2020 15:25:14 |

US3292236

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Aug 2020' | System | 20 Aug 2020 15:25:14 |

US3292236

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2020' | System | 20 Aug 2020 15:25:14 |

US3292236

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:29

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:44:53 |
| User entered 'Amendment 2 (2)' | Nathan Cortez (b) (4) | 20 Aug 2020 15:25:14 |

US3292236

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:44:53 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 20 Aug 2020 15:25:14 |

US3292236

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:29

If No, indicate reason for screen fail

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:44:53 |
| User entered empty. | Nathan Cortez (b) (4) | 20 Aug 2020 15:25:14 |

US3292236

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:29

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:44:53 |
| User entered empty. | Nathan Cortez (b) (4) | 20 Aug 2020 15:25:14 |

US3292236

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:29

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:44:53 |
| User entered 'No (N)' | Nathan Cortez (b) (4) | 20 Aug 2020 15:25:14 |

US3292236

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:29

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:44:53 |
| User entered empty. | RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 13:54:54 |

US3292236

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:29

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 20 Aug 2020 15:25:21 |

US3292236

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:45:02 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 20 Aug 2020 15:25:21 |

US3292236

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:56:29

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Query 'Nausea was listed on Discharge Summary. Please confirm and consider updating MH.' canceled (Site from CRA). | (b) (4), (b) (6) | 23 Oct 2020 19:54:33 |
| Query 'Diagnosis of Vertigo was listed on Discharge Summary. Please confirm and consider updating MH.' canceled (Site from CRA). | (b) (4), (b) (6) | 23 Oct 2020 19:54:31 |
| User opened query 'Nausea was listed on Discharge Summary. Please confirm and consider updating MH.' (Site from CRA). | (b) (4), (b) (6) | 21 Oct 2020 18:36:29 |
| User opened query 'Diagnosis of Vertigo was listed on Discharge Summary. Please confirm and consider updating MH.' (Site from CRA). | (b) (4), (b) (6) | 21 Oct 2020 18:35:46 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:45:14 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 13:20:47 |

US3292236

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:29

[Condition](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 13:25:24 |
| 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 13:25:24 |
| Data point term sent to Coder | System | 21 Aug 2020 13:24:07 |
| User entered 'Seasonal allergies' | (b) (4), (b) (6) | 21 Aug 2020 13:23:52 |

US3292236

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'un UNK 1972' | (b) (4), (b) (6) | 21 Aug 2020 13:23:52 |

US3292236

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:29

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:23:52 |

US3292236

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:29

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 13:23:52 |

US3292236

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:23:52 |

US3292236

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:29

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:23:52 |

US3292236

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 1972' | System | 21 Aug 2020 13:23:52 |

US3292236

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1972' | System | 21 Aug 2020 13:23:52 |

US3292236

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 13:23:52 |

US3292236

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 13:23:52 |

US3292236

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:29

[Condition](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Soy allergy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 24 Aug 2020 04:51:47 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 24 Aug 2020 04:51:47 |
| Data point term sent to Coder | System | 21 Aug 2020 13:25:08 |
| User entered 'Allergies to soy' | (b) (4), (b) (6) | 21 Aug 2020 13:24:12 |

US3292236

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'un UNK 1987' | (b) (4), (b) (6) | 21 Aug 2020 13:24:12 |

US3292236

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:29

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:24:12 |

US3292236

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:29

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 13:24:12 |

US3292236

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:24:12 |

US3292236

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:29

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:24:12 |

US3292236

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 1987' | System | 21 Aug 2020 13:24:12 |

US3292236

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1987' | System | 21 Aug 2020 13:24:12 |

US3292236

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 13:24:12 |

US3292236

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 13:24:12 |

US3292236

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:29

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User closed query 'Per DM CLR: Please review this Condition and please note that this information is not reflected on the Childbearing Potential eCRF page. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified. | (b) (4), (b) (6) | 11 Nov 2020 22:20:39 |
| Query 'Per DM CLR: Please review this Condition and please note that this information is not reflected on the Childbearing Potential eCRF page. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' answered with 'related to uterine fibroids' (Site from DM). | (b) (4), (b) (6) | 21 Sep 2020 19:34:36 |
| User opened query 'Per DM CLR: Please review this Condition and please note that this information is not reflected on the Childbearing Potential eCRF page. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 21 Sep 2020 13:01:31 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 13:25:25 |
| 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 13:25:25 |
| Data point term sent to Coder | System | 21 Aug 2020 13:25:08 |
| User entered 'Hysterectomy' | (b) (4), (b) (6) | 21 Aug 2020 13:24:42 |

US3292236

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'un UNK 1979' | (b) (4), (b) (6) | 21 Aug 2020 13:24:42 |

US3292236

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:29

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:24:42 |

US3292236

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:29

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:24:42 |

US3292236

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'un UNK 1979' | (b) (4), (b) (6) | 21 Aug 2020 13:24:42 |

US3292236

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:29

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:24:42 |

US3292236

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 1979' | System | 21 Aug 2020 13:24:42 |

US3292236

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1979' | System | 21 Aug 2020 13:24:42 |

US3292236

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 1979' | System | 21 Aug 2020 13:24:42 |

US3292236

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1979' | System | 21 Aug 2020 13:24:42 |

US3292236

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:29

Condition

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User closed query 'Please confirm reason for hospitalization. Per source, indication was pneumonia.' (Site from CRA). DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:30:34 |
| | (b) (4), (b) (6) | 21 Oct 2020 17:33:18 |
| User coded data point as SOC: Infections and infestations, HLG: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\23.0. | Coder Import (b) (4) | 05 Oct 2020 15:42:23 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 05 Oct 2020 15:42:23 |
| Data point term sent to Coder | System | 05 Oct 2020 15:41:56 |
| Query 'Please confirm reason for hospitalization. Per source, indication was pneumonia.' answered with 'updated' (Site from CRA). | (b) (4), (b) (6) | 05 Oct 2020 15:41:44 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 05 Oct 2020 15:41:37 |
| | (b) (4), (b) (6) | |
| Coding entries removed. | (b) (4), (b) (6) | 05 Oct 2020 15:41:37 |
| | (b) (4), (b) (6) | 05 Oct 2020 15:41:37 |
| User entered 'HOSPITALIZATION - Pneumonia' reason for change: Data Entry Error | (b) (4), (b) (6) | 05 Oct 2020 15:41:37 |
| | (b) (4), (b) (6) | 01 Oct 2020 17:50:29 |
| User opened query 'Please confirm reason for hospitalization. Per source, indication was pneumonia.' (Site from CRA). DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| | (b) (4), (b) (6) | |
| User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\23.0. | Coder Import (b) (4) | 22 Aug 2020 08:27:15 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 22 Aug 2020 08:27:15 |
| Data point term sent to Coder | System | 21 Aug 2020 13:27:12 |
| User entered 'Hospitalization - depression' | (b) (4), (b) (6) | 21 Aug 2020 13:26:51 |
| | (b) (4), (b) (6) | |

US3292236

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'un UNK 1990' | (b) (4), (b) (6) | 21 Aug 2020 13:26:51 |

US3292236

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:29

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:26:51 |

US3292236

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:29

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:26:51 |

US3292236

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'un UNK 1990' | (b) (4), (b) (6) | 21 Aug 2020 13:26:51 |

US3292236

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:29

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:26:51 |

US3292236

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 1990' | System | 21 Aug 2020 13:26:51 |

US3292236

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1990' | System | 21 Aug 2020 13:26:51 |

US3292236

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 1990' | System | 21 Aug 2020 13:26:51 |

US3292236

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1990' | System | 21 Aug 2020 13:26:51 |

US3292236

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:29

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Aug 2020 08:27:15 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Aug 2020 08:27:15 |
| Data point term sent to Coder | System | 21 Aug 2020 13:28:18 |
| User entered 'Hospitalization - pneumonia' | (b) (4), (b) (6) | 21 Aug 2020 13:27:46 |

US3292236

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'un UNK 2019' | (b) (4), (b) (6) | 21 Aug 2020 13:27:46 |

US3292236

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:29

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:27:46 |

US3292236

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:29

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:27:46 |

US3292236

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'un UNK 2019' | (b) (4), (b) (6) | 21 Aug 2020 13:27:46 |

US3292236

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:29

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:27:46 |

US3292236

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2019' | System | 21 Aug 2020 13:27:46 |

US3292236

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2019' | System | 21 Aug 2020 13:27:46 |

US3292236

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2019' | System | 21 Aug 2020 13:27:46 |

US3292236

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2019' | System | 21 Aug 2020 13:27:46 |

US3292236

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:29

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Bilateral cataract extraction - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 24 Oct 2020 20:29:33 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 24 Oct 2020 20:29:33 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Bilateral cataract extraction - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Aug 2020 08:03:10 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Aug 2020 08:03:10 |
| Data point term sent to Coder | System | 21 Aug 2020 13:33:29 |
| User entered 'Cataract removal OU - bilateral' | (b) (4), (b) (6) | 21 Aug 2020 13:32:51 |

US3292236

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'un UNK 2016' | (b) (4), (b) (6) | 21 Aug 2020 13:32:51 |

US3292236

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:29

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:32:51 |

US3292236

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:29

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:32:51 |

US3292236

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'un UNK 2016' | (b) (4), (b) (6) | 21 Aug 2020 13:32:51 |

US3292236

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:29

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:32:51 |

US3292236

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2016' | System | 21 Aug 2020 13:32:51 |

US3292236

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2016' | System | 21 Aug 2020 13:32:51 |

US3292236

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2016' | System | 21 Aug 2020 13:32:51 |

US3292236

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2016' | System | 21 Aug 2020 13:32:51 |

US3292236

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:29

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal haemorrhages NEC, HLT: Non-site specific gastrointestinal haemorrhages, PT: Upper gastrointestinal haemorrhage, LLT: Upper gastrointestinal bleeding - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Aug 2020 09:38:12 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Aug 2020 09:38:12 |
| Data point term sent to Coder | System | 21 Aug 2020 13:34:30 |
| User entered 'Upper GI bleed' | (b) (4), (b) (6) | 21 Aug 2020 13:33:42 |

US3292236

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'un UNK 1986' | (b) (4), (b) (6) | 21 Aug 2020 13:33:42 |

US3292236

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:29

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:33:42 |

US3292236

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:29

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:33:42 |

US3292236

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'un UNK 1986' | (b) (4), (b) (6) | 21 Aug 2020 13:33:42 |

US3292236

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:29

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:33:42 |

US3292236

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 1986' | System | 21 Aug 2020 13:33:42 |

US3292236

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1986' | System | 21 Aug 2020 13:33:42 |

US3292236

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 1986' | System | 21 Aug 2020 13:33:42 |

US3292236

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1986' | System | 21 Aug 2020 13:33:42 |

US3292236

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:29

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness bilateral, LLT: Hearing loss bilateral - version MedDRA\\23.0. | Coder Import (b) (4) | 21 Aug 2020 13:35:17 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | (b) (4) | 21 Aug 2020 13:35:17 |
| Data point term sent to Coder | System | 21 Aug 2020 13:34:32 |
| User entered 'Bilateral hearing loss' | (b) (4), (b) (6) | 21 Aug 2020 13:34:17 |

US3292236

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'un UNK 1990' | (b) (4), (b) (6) | 21 Aug 2020 13:34:17 |

US3292236

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:29

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:34:17 |

US3292236

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:29

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 13:34:17 |

US3292236

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:34:17 |

US3292236

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:29

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:34:17 |

US3292236

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 1990' | System | 21 Aug 2020 13:34:17 |

US3292236

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1990' | System | 21 Aug 2020 13:34:17 |

US3292236

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 13:34:17 |

US3292236

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 13:34:17 |

US3292236

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:29

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| Query 'Per DM CLR: Please review the stop date of this MH as there was a noted procedure of MH #6 CATARACT REMOVAL OU - BILATERAL done last UN UNK 2016 that matches this condition. Note that associated conditions usually resolve within the timeframe of the procedure. Please correct dates or provide explanation for the Med History dates. ' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 21 Sep 2020 19:35:32 |
| User opened query 'Per DM CLR: Please review the stop date of this MH as there was a noted procedure of MH #6 CATARACT REMOVAL OU - BILATERAL done last UN UNK 2016 that matches this condition. Note that associated conditions usually resolve within the timeframe of the procedure. Please correct dates or provide explanation for the Med History dates. ' (Site from DM). | (b) (4), (b) (6) | 21 Sep 2020 13:02:23 |
| User coded data point as SOC: Eye disorders, HLGT: Coder Import Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\\23.0. | (b) (4) (b) (4) | 21 Aug 2020 13:36:19 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 21 Aug 2020 13:36:19 |
| Data point term sent to Coder | System | 21 Aug 2020 13:35:32 |
| User entered 'Cataracts OU' | (b) (4), (b) (6) | 21 Aug 2020 13:34:50 |

US3292236

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'un UNK 1986' | (b) (4), (b) (6) | 21 Aug 2020 13:34:50 |

US3292236

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:29

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:34:50 |

US3292236

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:29

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:34:50 |

US3292236

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'UN UNK 2016' reason for change: Data Entry Error | (b) (4), (b) (6) | 21 Sep 2020 19:35:26 |
| User entered 'un UNK 1986' | (b) (4), (b) (6) | 21 Aug 2020 13:34:50 |

US3292236

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:29

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:34:50 |

US3292236

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 1986' | System | 21 Aug 2020 13:34:50 |

US3292236

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1986' | System | 21 Aug 2020 13:34:50 |

US3292236

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2016' | System | 21 Sep 2020 19:35:26 |
| User entered 'Jan 1986' | System | 21 Aug 2020 13:34:50 |

US3292236

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2016' | System | 21 Sep 2020 19:35:26 |
| User entered '1986' | System | 21 Aug 2020 13:34:50 |

US3292236

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:29

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Gastric ulcers and perforation, PT: Gastric ulcer, LLT: Stomach ulcer - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 13:36:20 |
| 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 13:36:20 |
| Data point term sent to Coder | System | 21 Aug 2020 13:35:35 |
| User entered 'Stomach ulcer' | (b) (4), (b) (6) | 21 Aug 2020 13:35:13 |

US3292236

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'un UNK 1986' | (b) (4), (b) (6) | 21 Aug 2020 13:35:13 |

US3292236

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:29

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:35:13 |

US3292236

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:29

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:35:13 |

US3292236

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'un UNK 1986' | (b) (4), (b) (6) | 21 Aug 2020 13:35:13 |

US3292236

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:29

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:35:13 |

US3292236

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 1986' | System | 21 Aug 2020 13:35:13 |

US3292236

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1986' | System | 21 Aug 2020 13:35:13 |

US3292236

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 1986' | System | 21 Aug 2020 13:35:13 |

US3292236

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1986' | System | 21 Aug 2020 13:35:13 |

US3292236

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:29

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 13:37:32 |
| 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 13:37:32 |
| Data point term sent to Coder | System | 21 Aug 2020 13:36:36 |
| User entered 'Hyperlipidemia' | (b) (4), (b) (6) | 21 Aug 2020 13:35:42 |

US3292236

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'un UNK 2015' | (b) (4), (b) (6) | 21 Aug 2020 13:35:42 |

US3292236

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:29

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:35:42 |

US3292236

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:29

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 13:35:42 |

US3292236

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:35:42 |

US3292236

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:29

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:35:42 |

US3292236

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2015' | System | 21 Aug 2020 13:35:42 |

US3292236

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2015' | System | 21 Aug 2020 13:35:42 |

US3292236

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 13:35:42 |

US3292236

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 13:35:42 |

US3292236

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:29

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Miscellaneous and site unspecified neoplasms malignant and unspecified, HLT: Neoplasms malignant site unspecified NEC, PT: Squamous cell carcinoma, LLT: Squamous cell carcinoma - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Aug 2020 09:31:20 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Aug 2020 09:31:20 |
| Data point term sent to Coder | System | 21 Aug 2020 13:37:42 |
| User entered 'Squamous cell cancer - RLE' | (b) (4), (b) (6) | 21 Aug 2020 13:37:34 |

US3292236

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'un UNK 2000' | (b) (4), (b) (6) | 21 Aug 2020 13:37:34 |

US3292236

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:29

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:37:34 |

US3292236

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:29

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:37:34 |

US3292236

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'un UNK 2000' | (b) (4), (b) (6) | 21 Aug 2020 13:37:34 |

US3292236

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:29

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:37:34 |

US3292236

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2000' | System | 21 Aug 2020 13:37:34 |

US3292236

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2000' | System | 21 Aug 2020 13:37:34 |

US3292236

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2000' | System | 21 Aug 2020 13:37:34 |

US3292236

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2000' | System | 21 Aug 2020 13:37:34 |

US3292236

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:29

[Condition](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\\23.0. | Coder Import (b) (4) | 21 Aug 2020 13:40:23 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 21 Aug 2020 13:40:23 |
| Data point term sent to Coder | System | 21 Aug 2020 13:38:42 |
| User entered 'Osteopenia' | (b) (4), (b) (6) | 21 Aug 2020 13:37:55 |

US3292236

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'un UNK 2000' | (b) (4), (b) (6) | 21 Aug 2020 13:37:55 |

US3292236

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:29

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:37:55 |

US3292236

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:29

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 13:37:55 |

US3292236

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:37:55 |

US3292236

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:29

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:37:55 |

US3292236

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2000' | System | 21 Aug 2020 13:37:55 |

US3292236

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2000' | System | 21 Aug 2020 13:37:55 |

US3292236

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 13:37:55 |

US3292236

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 13:37:55 |

US3292236

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:29

[Condition](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 13:40:24 |
| 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 13:40:24 |
| Data point term sent to Coder | System | 21 Aug 2020 13:38:43 |
| User entered 'Migraine headaches' | (b) (4), (b) (6) | 21 Aug 2020 13:38:24 |

US3292236

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'un UNK 1987' | (b) (4), (b) (6) | 21 Aug 2020 13:38:24 |

US3292236

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:29

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:38:24 |

US3292236

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:29

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 13:38:24 |

US3292236

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:38:24 |

US3292236

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:29

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:38:24 |

US3292236

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 1987' | System | 21 Aug 2020 13:38:24 |

US3292236

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1987' | System | 21 Aug 2020 13:38:24 |

US3292236

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 13:38:24 |

US3292236

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 13:38:24 |

US3292236

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:56:29

[Condition](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 13:40:24 |
| 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 13:40:24 |
| Data point term sent to Coder | System | 21 Aug 2020 13:39:43 |
| User entered 'Uterine fibroids' | (b) (4), (b) (6) | 21 Aug 2020 13:38:56 |

US3292236

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'un UNK 1979' | (b) (4), (b) (6) | 21 Aug 2020 13:38:56 |

US3292236

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:56:29

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:38:56 |

US3292236

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:56:29

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:38:56 |

US3292236

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered 'un UNK 1979' | (b) (4), (b) (6) | 21 Aug 2020 13:38:56 |

US3292236

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:56:29

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 17:46:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:38:56 |

US3292236

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 1979' | System | 21 Aug 2020 13:38:56 |

US3292236

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1979' | System | 21 Aug 2020 13:38:56 |

US3292236

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 1979' | System | 21 Aug 2020 13:38:56 |

US3292236

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1979' | System | 21 Aug 2020 13:38:56 |

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:02:45 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 13:40:25 |

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:02:45 |
| User entered '20 Aug 2020' | (b) (4), (b) (6) | 21 Aug 2020 13:40:25 |

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:02:45 |
| User entered '08:36' | (b) (4), (b) (6) | 21 Aug 2020 13:40:25 |

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 08:36' | System | 21 Aug 2020 13:40:25 |

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

[Height \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:02:45 |
| User entered '171.0' cm | (b) (4), (b) (6) | 21 Aug 2020 13:40:25 |
| DataPoint set to visible. | System | 20 Aug 2020 15:25:21 |

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

Weight (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:02:45 |
| User entered '59.7' kg | (b) (4), (b) (6) | 21 Aug 2020 13:40:25 |
| DataPoint set to visible. | System | 20 Aug 2020 15:25:21 |

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

[BMI \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: User entered '20.41654' | System | 17 Sep 2020 00:15:42 |
| User entered '20.4' | System | 21 Aug 2020 13:40:25 |
| DataPoint set to visible. | System | 20 Aug 2020 15:25:21 |

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|--------|----------------------|
| User entered 'kg/m2' | System | 21 Aug 2020 13:40:25 |
| DataPoint set to visible. | System | 20 Aug 2020 15:25:21 |

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:02:45 |
| User closed query 'Per CDM: Response noted; however 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 14:08:50 |
| Query 'Per CDM: Response noted; however 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 18:20:31 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 22 Sep 2020 18:20:26 |
| User opened query 'Per CDM: Response noted; however 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) | 24 Aug 2020 19:04:35 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 24 Aug 2020 19:04:26 |
| Query 'Data is required. Please provide.' answered with 'ND' (Site from System). | (b) (4), (b) (6) | 21 Aug 2020 13:42:57 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 21 Aug 2020 13:40:25 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:40:25 |

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:02:45 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:40:25 |

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:02:45 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:40:25 |

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| 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 10:51:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 17:35:35 |
| 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 17:59:57 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 07 Oct 2020 17:59:49 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 07 Oct 2020 17:59:49 |
| 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 12:43:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:02:45 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 24 Aug 2020 19:04:37 |
| Query 'Data is required. Please provide.' answered with 'ND' (Site from System). | (b) (4), (b) (6) | 21 Aug 2020 13:43:12 |
| User opened query 'Data is required. Please provide.' System (Site from System). | | 21 Aug 2020 13:40:25 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:40:25 |

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'bpm' | System | 07 Oct 2020 17:59:49 |
| User entered empty. | System | 21 Aug 2020 13:40:25 |

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| 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 10:51:57 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 17:35:35 |
| 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 18:00:03 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 07 Oct 2020 17:59:49 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 07 Oct 2020 17:59:49 |
| 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 12:43:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:02:45 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 24 Aug 2020 19:04:39 |
| Query 'Data is required. Please provide.' answered with 'ND' (Site from System). | (b) (4), (b) (6) | 21 Aug 2020 13:43:16 |
| User opened query 'Data is required. Please provide.' System (Site from System). | | 21 Aug 2020 13:40:25 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:40:25 |

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 07 Oct 2020 17:59:49 |
| User entered empty. | System | 21 Aug 2020 13:40:25 |

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| 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 10:52:20 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 17:35:35 |
| 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 18:00:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 07 Oct 2020 17:59:49 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 07 Oct 2020 17:59:49 |
| 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 12:43:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:02:45 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 24 Aug 2020 19:04:40 |
| Query 'Data is required. Please provide.' answered with 'ND' (Site from System). | (b) (4), (b) (6) | 21 Aug 2020 13:43:20 |
| User opened query 'Data is required. Please provide.' System (Site from System). | | 21 Aug 2020 13:40:25 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:40:25 |

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 07 Oct 2020 17:59:49 |
| User entered empty. | System | 21 Aug 2020 13:40:25 |

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| 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 10:52:41 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 17:35:35 |
| 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 18:00:14 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 07 Oct 2020 17:59:49 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 07 Oct 2020 17:59:49 |
| 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 12:43:45 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:02:45 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 24 Aug 2020 19:04:42 |
| Query 'Data is required. Please provide.' answered with 'ND' (Site from System). | (b) (4), (b) (6) | 21 Aug 2020 13:43:24 |
| User opened query 'Data is required. Please provide.' System (Site from System). | | 21 Aug 2020 13:40:25 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:40:25 |

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 07 Oct 2020 17:59:49 |
| User entered empty. | System | 21 Aug 2020 13:40:25 |

US3292236

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:29

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:03:44 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 13:43:55 |

US3292236

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:29

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:03:44 |
| User entered '20 Aug 2020' | (b) (4), (b) (6) | 21 Aug 2020 13:43:55 |

US3292236

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:56:29

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:03:56 |
| User entered '20 Aug 2020' | Kevin Martinez (b) (4) | 21 Sep 2020 22:24:02 |
| | (b) (4) | |

US3292236

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:56:29

[Is the participant of childbearing potential?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:03:56 |
| User entered 'No (N)' | Kevin Martinez (b) (4) | 21 Sep 2020 22:24:02 |

US3292236

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:56:29

[If No, what is the reason?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:03:56 |
| User entered 'Surgically sterile (SURGICALLY STERILE)' | Kevin Martinez (b) (4) | 21 Sep 2020 22:24:02 |

US3292236

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:56:29

If Partner medically sterile or Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:03:56 |
| User entered empty. | Kevin Martinez (b) (4) | 21 Sep 2020 22:24:02 |
| | (b) (4) | |

US3292236

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:56:29

If Surgically sterile, date of surgery (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:03:56 |
| User entered 'un UNK 1979' | Kevin Martinez (b) (4) | 21 Sep 2020 22:24:02 |

US3292236

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:56:29

Date of surgery unknown

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:03:56 |
| User entered '0' | Kevin Martinez (b) (4) | 21 Sep 2020 22:24:02 |

US3292236

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:56:29

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:03:56 |
| User entered empty. | Kevin Martinez (b) (4) | 21 Sep 2020 22:24:02 |
| | (b) (4) | |

US3292236

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:56:29

[Date of last menstruation unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:03:56 |
| User entered '0' | Kevin Martinez (b) (4) | 21 Sep 2020 22:24:02 |

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:29

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:04:29 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:44:39 |

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:29

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:04:29 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:44:39 |

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:29

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:04:29 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:44:39 |

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:29

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:04:29 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:44:39 |

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:29

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:04:29 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:44:39 |

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:29

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:04:29 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:44:39 |

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:29

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:04:29 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:44:39 |

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:29

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:04:29 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:44:39 |

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:29

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:04:29 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:44:39 |

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:29

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:04:29 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:44:39 |

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:29

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:04:29 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:44:39 |

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:29

[Other](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:04:29 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:44:39 |

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:29

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:04:29 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:44:39 |

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:29

No Risk Identified

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:44:39 |

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:29

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:04:29 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:44:39 |

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:29

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:04:29 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:44:39 |

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:29

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:04:29 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:44:39 |

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:29

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:04:29 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:44:39 |

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:29

[Resides in a single family home](#) (i.e., detached housing)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:04:29 |
| User entered '1' | (b) (4), (b) (6) | 21 Aug 2020 13:44:39 |

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:29

[Other](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:44:39 |

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:29

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:04:29 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:44:39 |

US3292236

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:56:29

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:05:16 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 13:53:17 |

US3292236

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:05:16 |
| User entered '20 Aug 2020' | (b) (4), (b) (6) | 21 Aug 2020 13:53:17 |

US3292236

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:05:16 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 21 Aug 2020 13:53:17 |

US3292236

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:56:29

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'VISIT1' | System | 21 Aug 2020 13:53:17 |

US3292236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:10 |
| User entered '20 AUG 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 14:49:27 |

US3292236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:29

[What was the participant's randomization number?](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:10 |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 21 Aug 2020 05:49:13 |
| Amendment Manager: Data point set to conformant. | System | 21 Aug 2020 05:49:13 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 20 Aug 2020 14:49:27 |
| User entered '187235' (non-conformant). | RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 14:49:27 |

US3292236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:29

[In what Cohort was the participant enrolled?](#)

| Audit | User | Time (GMT) |
|-------------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:10 |
| User entered '>=65 years (3)' | RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 14:49:27 |

US3292236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:29

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:10 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:54:44 |

US3292236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:29

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:10 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:54:44 |

US3292236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:29

Severe obesity (body mass index > or = 40kg/m2)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:10 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:54:44 |

US3292236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:29

Diabetes (Type I, Type 2, or gestational)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:10 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:54:44 |

US3292236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:29

[Liver Disease](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:10 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:54:44 |

US3292236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:29

[Human Immunodeficiency Virus \(HIV\) infection](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:10 |
| User entered 'No (N)' | Kevin Martinez (b) (4) | 21 Sep 2020 22:24:15 |
| Amendment Manager: DataPoint set to visible. | (b) (4) | 19 Sep 2020 10:36:42 |
| Amendment Manager inserted this DataPoint. | System | 19 Sep 2020 01:42:06 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:56:29

[Height](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 21 Aug 2020 14:02:26 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:56:29

[Weight](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 21 Aug 2020 14:02:26 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:56:29

[Height](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 21 Aug 2020 14:02:26 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:56:29

[Weight](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 21 Aug 2020 14:02:26 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 21 Aug 2020 14:02:26 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 14:02:26 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| User entered '20 Aug 2020' | (b) (4), (b) (6) | 21 Aug 2020 14:02:26 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| User entered '09:14' | (b) (4), (b) (6) | 21 Aug 2020 14:02:26 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 09:14' | System | 21 Aug 2020 14:02:26 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| User entered '36.8' C | (b) (4), (b) (6) | 21 Aug 2020 14:02:26 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 21 Aug 2020 14:02:26 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 14:02:26 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| User entered '72' | (b) (4), (b) (6) | 21 Aug 2020 14:02:26 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 21 Aug 2020 14:02:26 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| User entered '16' | (b) (4), (b) (6) | 21 Aug 2020 14:02:26 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 21 Aug 2020 14:02:26 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| User entered '115' | (b) (4), (b) (6) | 21 Aug 2020 14:02:26 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 21 Aug 2020 14:02:26 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). DataPoint Verified. | (b) (4), (b) (6) | 02 Nov 2020 15:22:23 |
| | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'normal per PI.' (Site from System). | Kevin Martinez (b) (4) | 21 Sep 2020 22:25:03 |
| Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | System | 17 Sep 2020 00:15:42 |
| User entered '59' | (b) (4), (b) (6) | 21 Aug 2020 14:02:26 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 21 Aug 2020 14:02:26 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:56:29

[Height](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 21 Aug 2020 14:02:26 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:56:29

[Weight](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 21 Aug 2020 14:02:26 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 21 Aug 2020 14:03:17 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 14:03:17 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| User entered '20 Aug 2020' | (b) (4), (b) (6) | 21 Aug 2020 14:03:17 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| User entered '10:47' | (b) (4), (b) (6) | 21 Aug 2020 14:03:17 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 10:47' | System | 21 Aug 2020 14:03:17 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| User entered '36.4' C | (b) (4), (b) (6) | 21 Aug 2020 14:03:17 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 21 Aug 2020 14:03:17 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 14:03:17 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| User entered '62' | (b) (4), (b) (6) | 21 Aug 2020 14:03:17 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 21 Aug 2020 14:03:17 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| User entered '20' | (b) (4), (b) (6) | 21 Aug 2020 14:03:17 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 21 Aug 2020 14:03:17 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| User entered '114' | (b) (4), (b) (6) | 21 Aug 2020 14:03:17 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 21 Aug 2020 14:03:17 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:07:52 |
| User entered '60' | (b) (4), (b) (6) | 21 Aug 2020 14:03:17 |

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 21 Aug 2020 14:03:17 |

US3292236

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:29

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:09:15 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 14:04:29 |

US3292236

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:29

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:09:15 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 14:04:29 |

US3292236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:29

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:09:22 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 20 Aug 2020 15:25:41 |

US3292236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:29

If No, reason not given

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:09:22 |
| User entered empty. | Nathan Cortez (b) (4) | 20 Aug 2020 15:25:41 |

US3292236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:09:22 |
| User entered empty. | Nathan Cortez (b) (4) | 20 Aug 2020 15:25:41 |

US3292236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:29

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:29

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:09:22 |
| User entered '20 Aug 2020' | Nathan Cortez (b) (4) | 20 Aug 2020 15:25:41 |

US3292236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:29

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|----------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:09:22 |
| User entered '10:14' | Nathan Cortez (b) (4) | 20 Aug 2020 15:25:41 |

US3292236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:29

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 10:14' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:29

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:09:22 |
| User entered 'Left Arm (LEFT ARM)' | Nathan Cortez (b) (4) | 20 Aug 2020 15:25:41 |

US3292236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:29

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:09:22 |
| User entered 'ONCE' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:29

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:29

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:10:41 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 14:03:42 |

US3292236

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:29

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:10:41 |
| User entered '20 Aug 2020' | (b) (4), (b) (6) | 21 Aug 2020 14:03:42 |

US3292236

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:29

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:10:41 |
| User entered '09:37' | (b) (4), (b) (6) | 21 Aug 2020 14:03:42 |

US3292236

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:29

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 09:37' | System | 21 Aug 2020 14:03:42 |

US3292236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:56:29

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:11:04 |
| User entered '20 Aug 2020' | (b) (4), (b) (6) | 21 Aug 2020 14:04:04 |

US3292236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:29

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | (b) (4), (b) (6) | 21 Aug 2020 14:04:04 |

US3292236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:29

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:11:04 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 14:04:04 |

US3292236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:29

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:11:04 |
| User entered '09:27' | (b) (4), (b) (6) | 21 Aug 2020 14:04:04 |

US3292236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:29

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 09:27' | System | 21 Aug 2020 14:04:04 |

US3292236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:56:29

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | (b) (4), (b) (6) | 21 Aug 2020 14:04:11 |

US3292236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:56:29

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:11:04 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 14:04:11 |

US3292236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:56:29

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:11:04 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 14:04:11 |

US3292236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:56:29

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 14:04:11 |

US3292236

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:11:17 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 14:04:17 |

US3292236

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 21 Aug 2020 14:04:17 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T10:59:03', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '832e1cb4-44f0-4ffd-bfa2-3537c1d043f2' | System | 20 Aug 2020 15:59:48 |
| User entered 'Yes (Y)' | System | 20 Aug 2020 15:59:48 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T10:59:18', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '832e1cb4-44f0-4ffd-bfa2-3537c1d043f2' | System | 20 Aug 2020 15:59:48 |
| User entered '97.5' | System | 20 Aug 2020 15:59:48 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T10:59:26', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '832e1cb4-44f0-4ffd-bfa2-3537c1d043f2' | System | 20 Aug 2020 15:59:48 |
| User entered 'No (N)' | System | 20 Aug 2020 15:59:48 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T10:59:43', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '832e1cb4-44f0-4ffd-bfa2-3537c1d043f2' | System | 20 Aug 2020 15:59:48 |
| User entered '20 Aug 2020 10:59' | System | 20 Aug 2020 15:59:48 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 10:34' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 13:04' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 1, after vaccination (at home)' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:26:43', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '28d7d1f6-f9eb-4005-abdc-f287a0a02101' | System | 20 Aug 2020 23:27:37 |
| User entered 'Yes (Y)' | System | 20 Aug 2020 23:27:37 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:26:54', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '28d7d1f6-f9eb-4005-abdc-f287a0a02101' | System | 20 Aug 2020 23:27:37 |
| User entered '97.3' | System | 20 Aug 2020 23:27:37 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

Was any MEDICATION TAKEN today for pain or fever?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:27:04', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '28d7d1f6-f9eb-4005-abdc-f287a0a02101' | System | 20 Aug 2020 23:27:37 |
| User entered 'No (N)' | System | 20 Aug 2020 23:27:37 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:27:34', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '28d7d1f6-f9eb-4005-abdc-f287a0a02101' | System | 20 Aug 2020 23:27:37 |
| User entered '20 Aug 2020 18:27' | System | 20 Aug 2020 23:27:37 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 13:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 11:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 2' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:29

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:03:29', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5dcfa22-5dd9-41e5-824a-54dc4d338406' | System | 21 Aug 2020 20:04:49 |
| User entered 'Yes (Y)' | System | 21 Aug 2020 20:04:49 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:29

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:04:22', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5dcfa22-5dd9-41e5-824a-54dc4d338406' | System | 21 Aug 2020 20:04:49 |
| User entered '96.7' | System | 21 Aug 2020 20:04:49 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:04:28', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5dcfa22-5dd9-41e5-824a-54dc4d338406' | System | 21 Aug 2020 20:04:49 |
| User entered 'No (N)' | System | 21 Aug 2020 20:04:49 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:04:44', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5dcfa22-5dd9-41e5-824a-54dc4d338406' | System | 21 Aug 2020 20:04:49 |
| User entered '21 Aug 2020 15:04' | System | 21 Aug 2020 20:04:49 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 12:00' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 11:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 3' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:29

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:02:17', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '160a7b22-0be5-42fd-9fc4-6ee13899f23b' | System | 22 Aug 2020 23:03:00 |
| User entered 'Yes (Y)' | System | 22 Aug 2020 23:03:00 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:29

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:02:31', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '160a7b22-0be5-42fd-9fc4-6ee13899f23b' | System | 22 Aug 2020 23:03:00 |
| User entered '97.2' | System | 22 Aug 2020 23:03:00 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:02:40', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '160a7b22-0be5-42fd-9fc4-6ee13899f23b' | System | 22 Aug 2020 23:03:00 |
| User entered 'No (N)' | System | 22 Aug 2020 23:03:00 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:02:56', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '160a7b22-0be5-42fd-9fc4-6ee13899f23b' | System | 22 Aug 2020 23:03:00 |
| User entered '22 Aug 2020 18:02' | System | 22 Aug 2020 23:03:00 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 12:00' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 11:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 4' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:29

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:04:43', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '5b9ce84b-9b65-4f88-b471-ed0a1f5e8e0e' | System | 23 Aug 2020 23:05:38 |
| User entered 'Yes (Y)' | System | 23 Aug 2020 23:05:38 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:29

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:05:06', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '5b9ce84b-9b65-4f88-b471-ed0a1f5e8e0e' | System | 23 Aug 2020 23:05:38 |
| User entered '97.0' | System | 23 Aug 2020 23:05:38 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:05:22', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '5b9ce84b-9b65-4f88-b471-ed0a1f5e8e0e' | System | 23 Aug 2020 23:05:38 |
| User entered 'No (N)' | System | 23 Aug 2020 23:05:38 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:05:32', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '5b9ce84b-9b65-4f88-b471-ed0a1f5e8e0e' | System | 23 Aug 2020 23:05:38 |
| User entered '23 Aug 2020 18:05' | System | 23 Aug 2020 23:05:38 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 12:00' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 11:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 5' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:29

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:28:17', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '7c33810c-8d35-4a5b-80f9-97cb4542314e' | System | 25 Aug 2020 00:29:24 |
| User entered 'Yes (Y)' | System | 25 Aug 2020 00:29:24 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:29

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:29:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '7c33810c-8d35-4a5b-80f9-97cb4542314e' User entered '97.3' | System | 25 Aug 2020 00:29:24 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:29:09', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '7c33810c-8d35-4a5b-80f9-97cb4542314e' | System | 25 Aug 2020 00:29:24 |
| User entered 'No (N)' | System | 25 Aug 2020 00:29:24 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:29:22', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '7c33810c-8d35-4a5b-80f9-97cb4542314e' | System | 25 Aug 2020 00:29:24 |
| User entered '24 Aug 2020 19:29' | System | 25 Aug 2020 00:29:24 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 12:00' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 11:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 6' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:29

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:25:56', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '4e7339af-7723-487a-983e-3d43b5aebf56' | System | 25 Aug 2020 22:26:28 |
| User entered 'Yes (Y)' | System | 25 Aug 2020 22:26:28 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:29

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:26:08', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '4e7339af-7723-487a-983e-3d43b5aebf56' | System | 25 Aug 2020 22:26:28 |
| User entered '97.2' | System | 25 Aug 2020 22:26:28 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:26:15', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '4e7339af-7723-487a-983e-3d43b5aebf56' | System | 25 Aug 2020 22:26:28 |
| User entered 'No (N)' | System | 25 Aug 2020 22:26:28 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:26:23', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '4e7339af-7723-487a-983e-3d43b5aebf56' | System | 25 Aug 2020 22:26:28 |
| User entered '25 Aug 2020 17:26' | System | 25 Aug 2020 22:26:28 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 12:00' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 11:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 7' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:29

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:19:21', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9fd212af-e9de-4b70-afab-e400224a41fb' User entered 'Yes (Y)' | System | 26 Aug 2020 23:19:53 |
| | System | 26 Aug 2020 23:19:53 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:29

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:19:34', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9fd212af-e9de-4b70-afab-e400224a41fb' User entered '97.2' | System | 26 Aug 2020 23:19:53 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:19:39', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9fd212af-e9de-4b70-afab-e400224a41fb' User entered 'No (N)' | System | 26 Aug 2020 23:19:53 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:19:51', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9fd212af-e9de-4b70-afab-e400224a41fb' User entered '26 Aug 2020 18:19' | System | 26 Aug 2020 23:19:53 |
| | System | 26 Aug 2020 23:19:53 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 12:00' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 11:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T10:59:59', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '898b506a-7565-454a-9807-8babf10d4ee2' | System | 20 Aug 2020 16:00:27 |
| User entered 'None (1)' | System | 20 Aug 2020 16:00:27 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T11:00:03', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '898b506a-7565-454a-9807-8babf10d4ee2' | System | 20 Aug 2020 16:00:27 |
| User entered 'No (N)' | System | 20 Aug 2020 16:00:27 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T11:00:08', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '898b506a-7565-454a-9807-8babf10d4ee2' | System | 20 Aug 2020 16:00:27 |
| User entered 'No (N)' | System | 20 Aug 2020 16:00:27 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T11:00:14', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '898b506a-7565-454a-9807-8babf10d4ee2' | System | 20 Aug 2020 16:00:27 |
| User entered 'None (1)' | System | 20 Aug 2020 16:00:27 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T11:00:23', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '898b506a-7565-454a-9807-8babf10d4ee2' | System | 20 Aug 2020 16:00:27 |
| User entered '20 Aug 2020 11:00' | System | 20 Aug 2020 16:00:27 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 10:34' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 13:04' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 1, after vaccination (at home)' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:28:28', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '57641dc1-ecef-4b7b-a69b-a9bc5386980c' User entered 'None (1)' | System | 20 Aug 2020 23:29:01 |
| | System | 20 Aug 2020 23:29:01 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:28:33', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '57641dc1-ecef-4b7b-a69b-a9bc5386980c' | System | 20 Aug 2020 23:29:01 |
| User entered 'No (N)' | System | 20 Aug 2020 23:29:01 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:28:38', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '57641dc1-ecef-4b7b-a69b-a9bc5386980c' | System | 20 Aug 2020 23:29:01 |
| User entered 'No (N)' | System | 20 Aug 2020 23:29:01 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:28:45', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '57641dc1-ecef-4b7b-a69b-a9bc5386980c' User entered 'None (1)' | System | 20 Aug 2020 23:29:01 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:28:59', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '57641dc1-ecef-4b7b-a69b-a9bc5386980c' User entered '20 Aug 2020 18:28' | System | 20 Aug 2020 23:29:01 |
| | System | 20 Aug 2020 23:29:01 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 13:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 11:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 2' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:02:37', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '507a995e-ac48-4436-945a-2f9d1e867956' | System | 21 Aug 2020 20:03:10 |
| User entered 'None (1)' | System | 21 Aug 2020 20:03:10 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:02:42', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '507a995e-ac48-4436-945a-2f9d1e867956' | System | 21 Aug 2020 20:03:10 |
| User entered 'No (N)' | System | 21 Aug 2020 20:03:10 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:02:47', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '507a995e-ac48-4436-945a-2f9d1e867956' | System | 21 Aug 2020 20:03:10 |
| User entered 'No (N)' | System | 21 Aug 2020 20:03:10 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:02:51', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '507a995e-ac48-4436-945a-2f9d1e867956' | System | 21 Aug 2020 20:03:10 |
| User entered 'None (1)' | System | 21 Aug 2020 20:03:10 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:03:06', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '507a995e-ac48-4436-945a-2f9d1e867956' | System | 21 Aug 2020 20:03:10 |
| User entered '21 Aug 2020 15:03' | System | 21 Aug 2020 20:03:10 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 12:00' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 11:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 3' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:03:06', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd31fa9c4-1269-470a-9a3f-6dae1fbd1ba9' | System | 22 Aug 2020 23:03:49 |
| User entered 'None (1)' | System | 22 Aug 2020 23:03:49 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:03:10', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd31fa9c4-1269-470a-9a3f-6dae1fbd1ba9' | System | 22 Aug 2020 23:03:49 |
| User entered 'No (N)' | System | 22 Aug 2020 23:03:49 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:03:16', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd31fa9c4-1269-470a-9a3f-6dae1fbd1ba9' | System | 22 Aug 2020 23:03:49 |
| User entered 'No (N)' | System | 22 Aug 2020 23:03:49 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:03:27', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd31fa9c4-1269-470a-9a3f-6dae1fbd1ba9' | System | 22 Aug 2020 23:03:49 |
| User entered 'None (1)' | System | 22 Aug 2020 23:03:49 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:03:47', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd31fa9c4-1269-470a-9a3f-6dae1fbd1ba9' | System | 22 Aug 2020 23:03:49 |
| User entered '22 Aug 2020 18:03' | System | 22 Aug 2020 23:03:49 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 12:00' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 11:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 4' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:05:40', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0a8f6960-c151-40b4-b10b-46fa53ba2fa6' | System | 23 Aug 2020 23:06:07 |
| User entered 'None (1)' | System | 23 Aug 2020 23:06:07 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:05:44', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0a8f6960-c151-40b4-b10b-46fa53ba2fa6' | System | 23 Aug 2020 23:06:07 |
| User entered 'No (N)' | System | 23 Aug 2020 23:06:07 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:05:48', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0a8f6960-c151-40b4-b10b-46fa53ba2fa6' | System | 23 Aug 2020 23:06:07 |
| User entered 'No (N)' | System | 23 Aug 2020 23:06:07 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:05:56', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0a8f6960-c151-40b4-b10b-46fa53ba2fa6' | System | 23 Aug 2020 23:06:07 |
| User entered 'None (1)' | System | 23 Aug 2020 23:06:07 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:06:06', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0a8f6960-c151-40b4-b10b-46fa53ba2fa6' | System | 23 Aug 2020 23:06:07 |
| User entered '23 Aug 2020 18:06' | System | 23 Aug 2020 23:06:07 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 12:00' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 11:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 5' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:29:31', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '8225e5f1-0299-40d8-859b-2eeb9ec5ea22' | System | 25 Aug 2020 00:29:59 |
| User entered 'None (1)' | System | 25 Aug 2020 00:29:59 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:29

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:29:35', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '8225e5f1-0299-40d8-859b-2eeb9ec5ea22' | System | 25 Aug 2020 00:29:59 |
| User entered 'No (N)' | System | 25 Aug 2020 00:29:59 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:29:40', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '8225e5f1-0299-40d8-859b-2eeb9ec5ea22' | System | 25 Aug 2020 00:29:59 |
| User entered 'No (N)' | System | 25 Aug 2020 00:29:59 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:29:44', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '8225e5f1-0299-40d8-859b-2eeb9ec5ea22' | System | 25 Aug 2020 00:29:59 |
| User entered 'None (1)' | System | 25 Aug 2020 00:29:59 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:29:57', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '8225e5f1-0299-40d8-859b-2eeb9ec5ea22' | System | 25 Aug 2020 00:29:59 |
| User entered '24 Aug 2020 19:29' | System | 25 Aug 2020 00:29:59 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 12:00' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 11:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 6' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:26:30', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '785dbbf-5593-42ff-914b-b2e3430a6ac5' | System | 25 Aug 2020 22:27:04 |
| User entered 'None (1)' | System | 25 Aug 2020 22:27:04 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:26:36', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '785dbbf-5593-42ff-914b-b2e3430a6ac5' | System | 25 Aug 2020 22:27:04 |
| User entered 'No (N)' | System | 25 Aug 2020 22:27:04 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:26:40', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '785dbbf-5593-42ff-914b-b2e3430a6ac5' | System | 25 Aug 2020 22:27:04 |
| User entered 'No (N)' | System | 25 Aug 2020 22:27:04 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:26:49', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '785dbbf-5593-42ff-914b-b2e3430a6ac5' | System | 25 Aug 2020 22:27:04 |
| User entered 'None (1)' | System | 25 Aug 2020 22:27:04 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:26:59', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '785dbbf-5593-42ff-914b-b2e3430a6ac5' | System | 25 Aug 2020 22:27:04 |
| User entered '25 Aug 2020 17:26' | System | 25 Aug 2020 22:27:04 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 12:00' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 11:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 7' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:19:57', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '47551128-9b2c-4723-851b-f4fa1c49f8ef' | System | 26 Aug 2020 23:20:35 |
| User entered 'None (1)' | System | 26 Aug 2020 23:20:35 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:29

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:20:01', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '47551128-9b2c-4723-851b-f4fa1c49f8ef' | System | 26 Aug 2020 23:20:35 |
| User entered 'No (N)' | System | 26 Aug 2020 23:20:35 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:20:07', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '47551128-9b2c-4723-851b-f4fa1c49f8ef' | System | 26 Aug 2020 23:20:35 |
| User entered 'No (N)' | System | 26 Aug 2020 23:20:35 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:20:18', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '47551128-9b2c-4723-851b-f4fa1c49f8ef' User entered 'None (1)' | System | 26 Aug 2020 23:20:35 |
| | System | 26 Aug 2020 23:20:35 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:20:29', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '47551128-9b2c-4723-851b-f4fa1c49f8ef' | System | 26 Aug 2020 23:20:35 |
| User entered '26 Aug 2020 18:20' | System | 26 Aug 2020 23:20:35 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 12:00' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 11:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T11:00:36', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '11174893-96c0-4f76-9cad-0228cf57e9cd' | System | 20 Aug 2020 16:02:15 |
| User entered 'None (0)' | System | 20 Aug 2020 16:02:15 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T11:00:44', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '11174893-96c0-4f76-9cad-0228cf57e9cd' | System | 20 Aug 2020 16:02:15 |
| User entered 'None (0)' | System | 20 Aug 2020 16:02:15 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T11:00:47', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '11174893-96c0-4f76-9cad-0228cf57e9cd' | System | 20 Aug 2020 16:02:15 |
| User entered 'None (0)' | System | 20 Aug 2020 16:02:15 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T11:00:51', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '11174893-96c0-4f76-9cad-0228cf57e9cd' | System | 20 Aug 2020 16:02:15 |
| User entered 'None (0)' | System | 20 Aug 2020 16:02:15 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T11:00:54', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '11174893-96c0-4f76-9cad-0228cf57e9cd' | System | 20 Aug 2020 16:02:15 |
| User entered 'None (0)' | System | 20 Aug 2020 16:02:15 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T11:00:59', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '11174893-96c0-4f76-9cad-0228cf57e9cd' | System | 20 Aug 2020 16:02:15 |
| User entered 'None (0)' | System | 20 Aug 2020 16:02:15 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T11:01:05', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '11174893-96c0-4f76-9cad-0228cf57e9cd' | System | 20 Aug 2020 16:02:15 |
| User entered 'No (N)' | System | 20 Aug 2020 16:02:15 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T11:01:25', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '11174893-96c0-4f76-9cad-0228cf57e9cd' | System | 20 Aug 2020 16:02:15 |
| User entered '20 Aug 2020 11:01' | System | 20 Aug 2020 16:02:15 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 10:34' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 13:04' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 1, after vaccination (at home)' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:29:36', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd49cb973-b9ad-4b1b-8672-6b591f80c19e' | System | 20 Aug 2020 23:30:24 |
| User entered 'None (0)' | System | 20 Aug 2020 23:30:24 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:29:40', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd49cb973-b9ad-4b1b-8672-6b591f80c19e' | System | 20 Aug 2020 23:30:24 |
| User entered 'None (0)' | System | 20 Aug 2020 23:30:24 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:29:44', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd49cb973-b9ad-4b1b-8672-6b591f80c19e' | System | 20 Aug 2020 23:30:24 |
| User entered 'None (0)' | System | 20 Aug 2020 23:30:24 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:29:48', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd49cb973-b9ad-4b1b-8672-6b591f80c19e' | System | 20 Aug 2020 23:30:24 |
| User entered 'None (0)' | System | 20 Aug 2020 23:30:24 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:29:52', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd49cb973-b9ad-4b1b-8672-6b591f80c19e' | System | 20 Aug 2020 23:30:24 |
| User entered 'None (0)' | System | 20 Aug 2020 23:30:24 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:29:56', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd49cb973-b9ad-4b1b-8672-6b591f80c19e' | System | 20 Aug 2020 23:30:24 |
| User entered 'None (0)' | System | 20 Aug 2020 23:30:24 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:30:05', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd49cb973-b9ad-4b1b-8672-6b591f80c19e' | System | 20 Aug 2020 23:30:24 |
| User entered 'No (N)' | System | 20 Aug 2020 23:30:24 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:30:19', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd49cb973-b9ad-4b1b-8672-6b591f80c19e' | System | 20 Aug 2020 23:30:24 |
| User entered '20 Aug 2020 18:30' | System | 20 Aug 2020 23:30:24 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 13:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 11:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 2' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:04:59', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c07687b-faaa-4d82-844a-9c45e51ed65c' | System | 21 Aug 2020 20:05:35 |
| User entered 'None (0)' | System | 21 Aug 2020 20:05:35 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:05:02', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c07687b-faaa-4d82-844a-9c45e51ed65c' | System | 21 Aug 2020 20:05:35 |
| User entered 'None (0)' | System | 21 Aug 2020 20:05:35 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:05:06', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c07687b-faaa-4d82-844a-9c45e51ed65c' | System | 21 Aug 2020 20:05:35 |
| User entered 'None (0)' | System | 21 Aug 2020 20:05:35 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:05:09', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c07687b-faaa-4d82-844a-9c45e51ed65c' | System | 21 Aug 2020 20:05:35 |
| User entered 'None (0)' | System | 21 Aug 2020 20:05:35 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:05:12', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c07687b-faaa-4d82-844a-9c45e51ed65c' | System | 21 Aug 2020 20:05:35 |
| User entered 'None (0)' | System | 21 Aug 2020 20:05:35 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:05:15', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c07687b-faaa-4d82-844a-9c45e51ed65c' | System | 21 Aug 2020 20:05:35 |
| User entered 'None (0)' | System | 21 Aug 2020 20:05:35 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:05:20', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c07687b-faaa-4d82-844a-9c45e51ed65c' | System | 21 Aug 2020 20:05:35 |
| User entered 'No (N)' | System | 21 Aug 2020 20:05:35 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:05:33', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c07687b-faaa-4d82-844a-9c45e51ed65c' User entered '21 Aug 2020 15:05' | System | 21 Aug 2020 20:05:35 |
| | System | 21 Aug 2020 20:05:35 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 12:00' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 11:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 3' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:03:57', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5075bcb-24da-4d4f-a395-1239d14750fb' User entered 'None (0)' | System | 22 Aug 2020 23:04:44 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:04:03', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5075bcb-24da-4d4f-a395-1239d14750fb' User entered 'None (0)' | System | 22 Aug 2020 23:04:44 |
| | System | 22 Aug 2020 23:04:44 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:04:08', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5075bcb-24da-4d4f-a395-1239d14750fb' User entered 'None (0)' | System | 22 Aug 2020 23:04:44 |
| | System | 22 Aug 2020 23:04:44 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:04:11', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5075bcb-24da-4d4f-a395-1239d14750fb' User entered 'None (0)' | System | 22 Aug 2020 23:04:44 |
| | System | 22 Aug 2020 23:04:44 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:04:14', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5075bcb-24da-4d4f-a395-1239d14750fb' User entered 'None (0)' | System | 22 Aug 2020 23:04:44 |
| | System | 22 Aug 2020 23:04:44 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:04:18', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5075bcb-24da-4d4f-a395-1239d14750fb' User entered 'None (0)' | System | 22 Aug 2020 23:04:44 |
| | System | 22 Aug 2020 23:04:44 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:04:27', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5075bcb-24da-4d4f-a395-1239d14750fb' | System | 22 Aug 2020 23:04:44 |
| User entered 'No (N)' | System | 22 Aug 2020 23:04:44 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:04:40', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5075bcb-24da-4d4f-a395-1239d14750fb' User entered '22 Aug 2020 18:04' | System | 22 Aug 2020 23:04:44 |
| | System | 22 Aug 2020 23:04:44 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 12:00' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 11:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 4' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:06:13', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '08d55264-0556-4fdb-b9ac-bce2bf2d4ad4' | System | 23 Aug 2020 23:06:51 |
| User entered 'None (0)' | System | 23 Aug 2020 23:06:51 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:06:16', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '08d55264-0556-4fdb-b9ac-bce2bf2d4ad4' | System | 23 Aug 2020 23:06:51 |
| User entered 'None (0)' | System | 23 Aug 2020 23:06:51 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:06:20', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '08d55264-0556-4fdb-b9ac-bce2bf2d4ad4' | System | 23 Aug 2020 23:06:51 |
| User entered 'None (0)' | System | 23 Aug 2020 23:06:51 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:06:25', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '08d55264-0556-4fdb-b9ac-bce2bf2d4ad4' | System | 23 Aug 2020 23:06:51 |
| User entered 'None (0)' | System | 23 Aug 2020 23:06:51 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:06:28', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '08d55264-0556-4fdb-b9ac-bce2bf2d4ad4' | System | 23 Aug 2020 23:06:51 |
| User entered 'None (0)' | System | 23 Aug 2020 23:06:51 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:06:31', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '08d55264-0556-4fdb-b9ac-bce2bf2d4ad4' | System | 23 Aug 2020 23:06:51 |
| User entered 'None (0)' | System | 23 Aug 2020 23:06:51 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:06:35', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '08d55264-0556-4fdb-b9ac-bce2bf2d4ad4' | System | 23 Aug 2020 23:06:51 |
| User entered 'No (N)' | System | 23 Aug 2020 23:06:51 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:06:47', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '08d55264-0556-4fdb-b9ac-bce2bf2d4ad4' | System | 23 Aug 2020 23:06:51 |
| User entered '23 Aug 2020 18:06' | System | 23 Aug 2020 23:06:51 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 12:00' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 11:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 5' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:30:02', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'ae3287b9-3d43-42b6-80f5-9a5c52da3470' | System | 25 Aug 2020 00:30:45 |
| User entered 'None (0)' | System | 25 Aug 2020 00:30:45 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:30:06', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'ae3287b9-3d43-42b6-80f5-9a5c52da3470' | System | 25 Aug 2020 00:30:45 |
| User entered 'None (0)' | System | 25 Aug 2020 00:30:45 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:30:09', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'ae3287b9-3d43-42b6-80f5-9a5c52da3470' | System | 25 Aug 2020 00:30:45 |
| User entered 'None (0)' | System | 25 Aug 2020 00:30:45 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:30:13', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'ae3287b9-3d43-42b6-80f5-9a5c52da3470' | System | 25 Aug 2020 00:30:45 |
| User entered 'None (0)' | System | 25 Aug 2020 00:30:45 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:30:16', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'ae3287b9-3d43-42b6-80f5-9a5c52da3470' | System | 25 Aug 2020 00:30:45 |
| User entered 'None (0)' | System | 25 Aug 2020 00:30:45 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:30:19', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'ae3287b9-3d43-42b6-80f5-9a5c52da3470' | System | 25 Aug 2020 00:30:45 |
| User entered 'None (0)' | System | 25 Aug 2020 00:30:45 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:30:27', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'ae3287b9-3d43-42b6-80f5-9a5c52da3470' | System | 25 Aug 2020 00:30:45 |
| User entered 'No (N)' | System | 25 Aug 2020 00:30:45 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:30:43', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'ae3287b9-3d43-42b6-80f5-9a5c52da3470' | System | 25 Aug 2020 00:30:45 |
| User entered '24 Aug 2020 19:30' | System | 25 Aug 2020 00:30:45 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 12:00' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 11:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 6' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:27:05', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '26e49f1f-0359-4a31-a129-d0b4f05deb84' | System | 25 Aug 2020 22:27:42 |
| User entered 'None (0)' | System | 25 Aug 2020 22:27:42 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:27:07', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '26e49f1f-0359-4a31-a129-d0b4f05deb84' | System | 25 Aug 2020 22:27:42 |
| User entered 'None (0)' | System | 25 Aug 2020 22:27:42 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:27:11', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '26e49f1f-0359-4a31-a129-d0b4f05deb84' | System | 25 Aug 2020 22:27:42 |
| User entered 'None (0)' | System | 25 Aug 2020 22:27:42 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:27:15', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '26e49f1f-0359-4a31-a129-d0b4f05deb84' | System | 25 Aug 2020 22:27:42 |
| User entered 'None (0)' | System | 25 Aug 2020 22:27:42 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:27:19', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '26e49f1f-0359-4a31-a129-d0b4f05deb84' | System | 25 Aug 2020 22:27:42 |
| User entered 'None (0)' | System | 25 Aug 2020 22:27:42 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:27:21', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '26e49f1f-0359-4a31-a129-d0b4f05deb84' | System | 25 Aug 2020 22:27:42 |
| User entered 'None (0)' | System | 25 Aug 2020 22:27:42 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:27:25', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '26e49f1f-0359-4a31-a129-d0b4f05deb84' | System | 25 Aug 2020 22:27:42 |
| User entered 'No (N)' | System | 25 Aug 2020 22:27:42 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:27:38', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '26e49f1f-0359-4a31-a129-d0b4f05deb84' | System | 25 Aug 2020 22:27:42 |
| User entered '25 Aug 2020 17:27' | System | 25 Aug 2020 22:27:42 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 12:00' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 11:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 7' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:20:38', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9bc9b411-2a55-4755-acff-8f14d68cd1bc' | System | 26 Aug 2020 23:21:13 |
| User entered 'None (0)' | System | 26 Aug 2020 23:21:13 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:20:41', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9bc9b411-2a55-4755-acff-8f14d68cd1bc' | System | 26 Aug 2020 23:21:13 |
| User entered 'None (0)' | System | 26 Aug 2020 23:21:13 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:20:44', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9bc9b411-2a55-4755-acff-8f14d68cd1bc' | System | 26 Aug 2020 23:21:13 |
| User entered 'None (0)' | System | 26 Aug 2020 23:21:13 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:20:48', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9bc9b411-2a55-4755-acff-8f14d68cd1bc' | System | 26 Aug 2020 23:21:13 |
| User entered 'None (0)' | System | 26 Aug 2020 23:21:13 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:20:51', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9bc9b411-2a55-4755-acff-8f14d68cd1bc' | System | 26 Aug 2020 23:21:13 |
| User entered 'None (0)' | System | 26 Aug 2020 23:21:13 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:20:54', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9bc9b411-2a55-4755-acff-8f14d68cd1bc' | System | 26 Aug 2020 23:21:13 |
| User entered 'None (0)' | System | 26 Aug 2020 23:21:13 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:20:58', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9bc9b411-2a55-4755-acff-8f14d68cd1bc' | System | 26 Aug 2020 23:21:13 |
| User entered 'No (N)' | System | 26 Aug 2020 23:21:13 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:21:08', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9bc9b411-2a55-4755-acff-8f14d68cd1bc' | System | 26 Aug 2020 23:21:13 |
| User entered '26 Aug 2020 18:21' | System | 26 Aug 2020 23:21:13 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 12:00' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 11:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:12:00 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 27 Aug 2020 18:12:28 |

US3292236

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:12:00 |
| User entered '27 Aug 2020' | Kristy Trevino (b) (4) (b) (4) | 27 Aug 2020 18:12:28 |

US3292236

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:12:00 |
| User entered 'Contact Made (CONTACT MADE)' | Kristy Trevino (b) (4) (b) (4) | 27 Aug 2020 18:12:28 |

US3292236

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:12:00 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 27 Aug 2020 18:12:28 |

US3292236

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:14:24 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 27 Aug 2020 18:12:36 |

US3292236

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 27 Aug 2020 18:12:36 |

US3292236

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:39:50 |
| User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System). | System | 03 Sep 2020 15:07:43 |
| User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System). | System | 03 Sep 2020 15:07:27 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 03 Sep 2020 15:07:27 |

US3292236

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Un-verified. | Antonio Gutierrez (b) (4) | 10 Nov 2020 14:31:39 |
| User entered '03 Sep 2020' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 10 Nov 2020 14:31:39 |
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:39:50 |
| User entered '3 Sep 2020' reason for change: Data Entry Error | Kristy Trevino (b) (4) | 03 Sep 2020 15:07:43 |
| User entered empty. | Kristy Trevino (b) (4) | 03 Sep 2020 15:07:27 |

US3292236

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:39:50 |
| User entered 'Contact Made (CONTACT MADE)' | Kristy Trevino (b) (4) (b) (4) | 03 Sep 2020 15:07:27 |

US3292236

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:39:50 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 03 Sep 2020 15:07:27 |

US3292236

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:40:04 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 03 Sep 2020 15:06:27 |

US3292236

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 03 Sep 2020 15:06:27 |

US3292236

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:43:18 |
| User entered 'Yes (Y)' | Kevin Martinez (b) (4) | 21 Sep 2020 22:28:16 |
| | (b) (4) | |

US3292236

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:43:18 |
| User entered '10 Sep 2020' | Kevin Martinez (b) (4) | 21 Sep 2020 22:28:16 |
| | (b) (4) | |

US3292236

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:43:18 |
| User entered 'Contact Not Made (CONTACT NOT MADE)' | Kevin Martinez (b) (4) | 21 Sep 2020 22:28:16 |

US3292236

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:43:18 |
| User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System). | System | 21 Sep 2020 22:29:14 |
| User entered 'Patient did not answer call.' reason for change: Data Entry Error | Kevin Martinez (b) (4) | 21 Sep 2020 22:29:14 |
| User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System). | (b) (4) | 21 Sep 2020 22:28:16 |
| User entered empty. | System | 21 Sep 2020 22:28:16 |
| | Kevin Martinez (b) (4) | 21 Sep 2020 22:28:16 |
| | (b) (4) | |

US3292236

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:43:28 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 17 Sep 2020 16:08:54 |

US3292236

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 17 Sep 2020 16:08:54 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:29

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:44:08 |
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:03:11 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:29

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| User closed query 'Per GCL Lab Recon: Sample for Visit 3 Day 57 dated Oct2020 is reported in PPD Central lab; however Visit is blank. Please reconcile. ' (Site from DM). | (b) (4), (b) (6) | 24 Nov 2020 09:52:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:44:08 |
| Query 'Per GCL Lab Recon: Sample for Visit 3 Day 57 dated Oct2020 is reported in PPD Central lab; however Visit is blank. Please reconcile. ' answered with 'UPDATED' (Site from DM). | Victoria Hernandez (b) (4) | 05 Nov 2020 19:46:22 |
| User opened query 'Per GCL Lab Recon: Sample for Visit 3 Day 57 dated Oct2020 is reported in PPD Central lab; however Visit is blank. Please reconcile. ' (Site from DM). | (b) (4), (b) (6) | 01 Nov 2020 01:31:19 |
| User entered '17 Sep 2020' | Gerardo Pena (b) (4) | 17 Sep 2020 17:03:11 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:44:08 |
| User entered 'Clinic (Clinic)' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:03:11 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:29

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'VISIT2' | System | 17 Sep 2020 17:03:11 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:03:47 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:10 |
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:03:47 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:10 |
| User entered '17 Sep 2020' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:03:47 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:10 |
| User entered '09:32' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:03:47 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 09:32' | System | 17 Sep 2020 17:03:47 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:10 |
| User entered '36.3' C | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:03:47 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:10 |
| User entered 'Oral (Oral)' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:03:47 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:10 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:03:47 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:10 |
| User entered '70' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:03:47 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 17 Sep 2020 17:03:47 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:10 |
| User entered '17' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:03:47 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 17 Sep 2020 17:03:47 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:10 |
| User entered '116' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:03:47 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 17 Sep 2020 17:03:47 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:10 |
| User entered '65' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:03:47 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:29

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 17 Sep 2020 17:03:47 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:04:37 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:10 |
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:04:37 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:10 |
| User entered '17 Sep 2020' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:04:37 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:10 |
| User entered '11:21' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:04:37 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 11:21' | System | 17 Sep 2020 17:04:37 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:10 |
| User entered '36.8' C | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:04:37 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:10 |
| User entered 'Oral (Oral)' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:04:37 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:10 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:04:37 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:10 |
| User entered '64' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:04:37 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 17 Sep 2020 17:04:37 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:10 |
| User entered '20' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:04:37 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 17 Sep 2020 17:04:37 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:10 |
| User entered '121' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:04:37 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 17 Sep 2020 17:04:37 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:10 |
| User entered '65' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:04:37 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:29

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 17 Sep 2020 17:04:37 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:29

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:30 |
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:04:48 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:29

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:30 |
| User entered '17 Sep 2020' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:04:48 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:29

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:42 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 17 Sep 2020 16:09:13 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:29

If No, reason not given

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:42 |
| User entered empty. | (b) (4), (b) (6) | 17 Sep 2020 16:09:13 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:42 |
| User entered empty. | (b) (4), (b) (6) | 17 Sep 2020 16:09:13 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:29

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:29

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:42 |
| User entered '17 Sep 2020' | (b) (4), (b) (6) | 17 Sep 2020 16:09:13 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:29

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:42 |
| User entered '10:49' | (b) (4), (b) (6) | 17 Sep 2020 16:09:13 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:29

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 10:49' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:29

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:42 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4), (b) (6) | 17 Sep 2020 16:09:13 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:29

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:42 |
| User entered 'ONCE' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:29

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:29

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:55 |
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:05:23 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:29

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:55 |
| User entered '17 Sep 2020' | Gerardo Pena (b) (4) | 17 Sep 2020 17:05:23 |
| | (b) (4) | |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:29

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|----------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:45:55 |
| User entered '09:42' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:05:23 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:29

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 09:42' | System | 17 Sep 2020 17:05:23 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:56:29

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:46:14 |
| User entered '17 Sep 2020' | Gerardo Pena (b) (4) | 17 Sep 2020 17:05:39 |
| | (b) (4) | |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:29

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:05:39 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:29

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:46:14 |
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:05:39 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:29

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|----------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:46:14 |
| User entered '10:00' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:05:39 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:29

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 10:00' | System | 17 Sep 2020 17:05:39 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:56:29

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:05:39 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:56:29

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:46:14 |
| User entered 'No (N)' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:05:39 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:56:29

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:46:14 |
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:05:39 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:56:29

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 17 Sep 2020 17:05:39 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:46:22 |
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 17 Sep 2020 17:05:48 |

US3292236

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Sep 2020 17:05:48 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 16:09:13 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:25:45', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '3a9acaeb-d473-4762-bce9-047364727148' | System | 17 Sep 2020 16:26:06 |
| User entered 'Yes (Y)' | System | 17 Sep 2020 16:26:06 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:25:24', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '3a9acaeb-d473-4762-bce9-047364727148' | System | 17 Sep 2020 16:26:06 |
| User entered '98.2' | System | 17 Sep 2020 16:26:06 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:25:36', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '3a9acaeb-d473-4762-bce9-047364727148' | System | 17 Sep 2020 16:26:06 |
| User entered 'No (N)' | System | 17 Sep 2020 16:26:06 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:26:02', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '3a9acaeb-d473-4762-bce9-047364727148' | System | 17 Sep 2020 16:26:06 |
| User entered '17 Sep 2020 11:26' | System | 17 Sep 2020 16:26:06 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 11:09' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 13:39' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 16:09:13 |
| User entered 'Day 1, after vaccination (at home)' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:44:12', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '395cd8c3-4d74-4990-8027-537fa21dd168' | System | 17 Sep 2020 20:44:41 |
| User entered 'Yes (Y)' | System | 17 Sep 2020 20:44:41 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:44:22', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '395cd8c3-4d74-4990-8027-537fa21dd168' | System | 17 Sep 2020 20:44:41 |
| User entered '94.4' | System | 17 Sep 2020 20:44:41 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:44:28', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '395cd8c3-4d74-4990-8027-537fa21dd168' | System | 17 Sep 2020 20:44:41 |
| User entered 'No (N)' | System | 17 Sep 2020 20:44:41 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:44:38', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '395cd8c3-4d74-4990-8027-537fa21dd168' | System | 17 Sep 2020 20:44:41 |
| User entered '17 Sep 2020 15:44' | System | 17 Sep 2020 20:44:41 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 14:34' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 11:59' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 16:09:13 |
| User entered 'Day 2' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:29

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:20:20', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '31390f3f-af0c-4cdc-96de-7864643f7340' | System | 18 Sep 2020 21:20:55 |
| User entered 'Yes (Y)' | System | 18 Sep 2020 21:20:55 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:29

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:20:31', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '31390f3f-af0c-4cdc-96de-7864643f7340' | System | 18 Sep 2020 21:20:55 |
| User entered '97.8' | System | 18 Sep 2020 21:20:55 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:20:40', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '31390f3f-af0c-4cdc-96de-7864643f7340' | System | 18 Sep 2020 21:20:55 |
| User entered 'No (N)' | System | 18 Sep 2020 21:20:55 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:20:51', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '31390f3f-af0c-4cdc-96de-7864643f7340' User entered '18 Sep 2020 16:20' | System | 18 Sep 2020 21:20:55 |
| | System | 18 Sep 2020 21:20:55 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 12:00' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 11:59' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 16:09:13 |
| User entered 'Day 3' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:29

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:02:50', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5a39625-e1d1-4873-b06e-5cbc336e24a5' | System | 20 Sep 2020 02:03:17 |
| User entered 'Yes (Y)' | System | 20 Sep 2020 02:03:17 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:29

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:02:59', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5a39625-e1d1-4873-b06e-5cbc336e24a5' | System | 20 Sep 2020 02:03:17 |
| User entered '97.8' | System | 20 Sep 2020 02:03:17 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:03:04', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5a39625-e1d1-4873-b06e-5cbc336e24a5' | System | 20 Sep 2020 02:03:17 |
| User entered 'No (N)' | System | 20 Sep 2020 02:03:17 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:03:13', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5a39625-e1d1-4873-b06e-5cbc336e24a5' | System | 20 Sep 2020 02:03:17 |
| User entered '19 Sep 2020 21:03' | System | 20 Sep 2020 02:03:17 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 12:00' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 11:59' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 16:09:13 |
| User entered 'Day 4' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:29

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:54:24', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '302686a2-73a4-440d-920a-d1728f377087' | System | 20 Sep 2020 23:54:49 |
| User entered 'Yes (Y)' | System | 20 Sep 2020 23:54:49 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:29

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:54:32', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '302686a2-73a4-440d-920a-d1728f377087' | System | 20 Sep 2020 23:54:49 |
| User entered '97.8' | System | 20 Sep 2020 23:54:49 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:54:39', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '302686a2-73a4-440d-920a-d1728f377087' | System | 20 Sep 2020 23:54:49 |
| User entered 'No (N)' | System | 20 Sep 2020 23:54:49 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:54:47', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '302686a2-73a4-440d-920a-d1728f377087' | System | 20 Sep 2020 23:54:49 |
| User entered '20 Sep 2020 18:54' | System | 20 Sep 2020 23:54:49 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 12:00' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 11:59' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 16:09:13 |
| User entered 'Day 5' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:29

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:20:05', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '32e23df3-55a5-46a8-88d3-5217584159af' | System | 21 Sep 2020 22:20:36 |
| User entered 'Yes (Y)' | System | 21 Sep 2020 22:20:36 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:29

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:20:12', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '32e23df3-55a5-46a8-88d3-5217584159af' | System | 21 Sep 2020 22:20:36 |
| User entered '97.8' | System | 21 Sep 2020 22:20:36 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:20:20', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '32e23df3-55a5-46a8-88d3-5217584159af' | System | 21 Sep 2020 22:20:36 |
| User entered 'No (N)' | System | 21 Sep 2020 22:20:36 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:20:33', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '32e23df3-55a5-46a8-88d3-5217584159af' User entered '21 Sep 2020 17:20' | System | 21 Sep 2020 22:20:36 |
| | System | 21 Sep 2020 22:20:36 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 12:00' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 11:59' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 16:09:13 |
| User entered 'Day 6' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:29

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:34:22', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '5526a3aa-54e1-4070-86ad-baf284e18fda' | System | 22 Sep 2020 22:34:54 |
| User entered 'Yes (Y)' | System | 22 Sep 2020 22:34:54 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:29

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:34:34', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '5526a3aa-54e1-4070-86ad-baf284e18fda' User entered '97.6' | System | 22 Sep 2020 22:34:54 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:34:44', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '5526a3aa-54e1-4070-86ad-baf284e18fda' | System | 22 Sep 2020 22:34:54 |
| User entered 'No (N)' | System | 22 Sep 2020 22:34:54 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:34:52', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '5526a3aa-54e1-4070-86ad-baf284e18fda' User entered '22 Sep 2020 17:34' | System | 22 Sep 2020 22:34:54 |
| | System | 22 Sep 2020 22:34:54 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 12:00' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 11:59' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 16:09:13 |
| User entered 'Day 7' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:29

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:17:03', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9f562f9b-6ef8-418c-8f32-8cea3fe617bd' | System | 24 Sep 2020 11:17:30 |
| User entered 'Yes (Y)' | System | 24 Sep 2020 11:17:30 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:29

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:17:14', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9f562f9b-6ef8-418c-8f32-8cea3fe617bd' | System | 24 Sep 2020 11:17:30 |
| User entered '97.4' | System | 24 Sep 2020 11:17:30 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:17:20', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9f562f9b-6ef8-418c-8f32-8cea3fe617bd' | System | 24 Sep 2020 11:17:30 |
| User entered 'No (N)' | System | 24 Sep 2020 11:17:30 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:17:27', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9f562f9b-6ef8-418c-8f32-8cea3fe617bd' User entered '24 Sep 2020 06:17' | System | 24 Sep 2020 11:17:30 |
| | System | 24 Sep 2020 11:17:30 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 12:00' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 11:59' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 16:09:13 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:26:15', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '43aa98bb-19dc-4cd1-9da7-7e17824fceed' | System | 17 Sep 2020 16:26:51 |
| User entered 'None (1)' | System | 17 Sep 2020 16:26:51 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:26:24', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '43aa98bb-19dc-4cd1-9da7-7e17824fceed' | System | 17 Sep 2020 16:26:51 |
| User entered 'No (N)' | System | 17 Sep 2020 16:26:51 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:26:29', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '43aa98bb-19dc-4cd1-9da7-7e17824fceed' | System | 17 Sep 2020 16:26:51 |
| User entered 'No (N)' | System | 17 Sep 2020 16:26:51 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:26:40', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '43aa98bb-19dc-4cd1-9da7-7e17824fceed' | System | 17 Sep 2020 16:26:51 |
| User entered 'None (1)' | System | 17 Sep 2020 16:26:51 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:26:48', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '43aa98bb-19dc-4cd1-9da7-7e17824fceed' | System | 17 Sep 2020 16:26:51 |
| User entered '17 Sep 2020 11:26' | System | 17 Sep 2020 16:26:51 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 11:09' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 13:39' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 16:09:13 |
| User entered 'Day 1, after vaccination (at home)' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:44:45', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '98846e73-d2c4-4f99-ad73-5e78c860138e' | System | 17 Sep 2020 20:45:18 |
| User entered 'None (1)' | System | 17 Sep 2020 20:45:18 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:44:50', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '98846e73-d2c4-4f99-ad73-5e78c860138e' | System | 17 Sep 2020 20:45:18 |
| User entered 'No (N)' | System | 17 Sep 2020 20:45:18 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:44:57', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '98846e73-d2c4-4f99-ad73-5e78c860138e' | System | 17 Sep 2020 20:45:18 |
| User entered 'No (N)' | System | 17 Sep 2020 20:45:18 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:45:02', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '98846e73-d2c4-4f99-ad73-5e78c860138e' User entered 'None (1)' | System | 17 Sep 2020 20:45:18 |
| | System | 17 Sep 2020 20:45:18 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:45:16', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '98846e73-d2c4-4f99-ad73-5e78c860138e' | System | 17 Sep 2020 20:45:18 |
| User entered '17 Sep 2020 15:45' | System | 17 Sep 2020 20:45:18 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 14:34' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 11:59' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 16:09:13 |
| User entered 'Day 2' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:21:02', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '25839774-93ed-45e1-abdd-2bd5ea7e4b1d' | System | 18 Sep 2020 21:21:39 |
| User entered 'None (1)' | System | 18 Sep 2020 21:21:39 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:29

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:21:09', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '25839774-93ed-45e1-abdd-2bd5ea7e4b1d' | System | 18 Sep 2020 21:21:39 |
| User entered 'No (N)' | System | 18 Sep 2020 21:21:39 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:21:16', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '25839774-93ed-45e1-abdd-2bd5ea7e4b1d' | System | 18 Sep 2020 21:21:39 |
| User entered 'No (N)' | System | 18 Sep 2020 21:21:39 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:21:28', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '25839774-93ed-45e1-abdd-2bd5ea7e4b1d' User entered 'None (1)' | System | 18 Sep 2020 21:21:39 |
| | System | 18 Sep 2020 21:21:39 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:21:37', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '25839774-93ed-45e1-abdd-2bd5ea7e4b1d' | System | 18 Sep 2020 21:21:39 |
| User entered '18 Sep 2020 16:21' | System | 18 Sep 2020 21:21:39 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 12:00' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 11:59' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 16:09:13 |
| User entered 'Day 3' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:03:23', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '419e7ce3-c0bf-41ab-a91e-83599dad7190' | System | 20 Sep 2020 02:04:04 |
| User entered 'None (1)' | System | 20 Sep 2020 02:04:04 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:03:27', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '419e7ce3-c0bf-41ab-a91e-83599dad7190' | System | 20 Sep 2020 02:04:04 |
| User entered 'No (N)' | System | 20 Sep 2020 02:04:04 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:03:33', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '419e7ce3-c0bf-41ab-a91e-83599dad7190' | System | 20 Sep 2020 02:04:04 |
| User entered 'No (N)' | System | 20 Sep 2020 02:04:04 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:03:43', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '419e7ce3-c0bf-41ab-a91e-83599dad7190' | System | 20 Sep 2020 02:04:04 |
| User entered 'None (1)' | System | 20 Sep 2020 02:04:04 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:03:55', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '419e7ce3-c0bf-41ab-a91e-83599dad7190' | System | 20 Sep 2020 02:04:04 |
| User entered '19 Sep 2020 21:03' | System | 20 Sep 2020 02:04:04 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 12:00' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 11:59' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 16:09:13 |
| User entered 'Day 4' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:54:55', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'bfaa9da3-c3c4-4805-a5ed-2d9d6bfd5019' | System | 20 Sep 2020 23:55:21 |
| User entered 'None (1)' | System | 20 Sep 2020 23:55:21 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:29

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:54:59', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'bfaa9da3-c3c4-4805-a5ed-2d9d6bfd5019' | System | 20 Sep 2020 23:55:21 |
| User entered 'No (N)' | System | 20 Sep 2020 23:55:21 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:55:04', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'bfaa9da3-c3c4-4805-a5ed-2d9d6bfd5019' | System | 20 Sep 2020 23:55:21 |
| User entered 'No (N)' | System | 20 Sep 2020 23:55:21 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:55:11', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'bfaa9da3-c3c4-4805-a5ed-2d9d6bfd5019' | System | 20 Sep 2020 23:55:21 |
| User entered 'None (1)' | System | 20 Sep 2020 23:55:21 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:55:20', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'bfaa9da3-c3c4-4805-a5ed-2d9d6bfd5019' | System | 20 Sep 2020 23:55:21 |
| User entered '20 Sep 2020 18:55' | System | 20 Sep 2020 23:55:21 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 12:00' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 11:59' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 16:09:13 |
| User entered 'Day 5' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:20:41', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '215aeba0-4efa-4de4-be2e-5316d426a68e' | System | 21 Sep 2020 22:21:14 |
| User entered 'None (1)' | System | 21 Sep 2020 22:21:14 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:20:45', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '215aeba0-4efa-4de4-be2e-5316d426a68e' | System | 21 Sep 2020 22:21:14 |
| User entered 'No (N)' | System | 21 Sep 2020 22:21:14 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:20:53', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '215aeba0-4efa-4de4-be2e-5316d426a68e' | System | 21 Sep 2020 22:21:14 |
| User entered 'No (N)' | System | 21 Sep 2020 22:21:14 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:20:58', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '215aeba0-4efa-4de4-be2e-5316d426a68e' | System | 21 Sep 2020 22:21:14 |
| User entered 'None (1)' | System | 21 Sep 2020 22:21:14 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:21:12', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '215aeba0-4efa-4de4-be2e-5316d426a68e' | System | 21 Sep 2020 22:21:14 |
| User entered '21 Sep 2020 17:21' | System | 21 Sep 2020 22:21:14 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 12:00' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 11:59' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 16:09:13 |
| User entered 'Day 6' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:29

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:35:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c946c9b-2848-4499-bb65-dc8d8f391127' | System | 22 Sep 2020 22:35:31 |
| User entered 'None (1)' | System | 22 Sep 2020 22:35:31 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:29

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:35:04', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c946c9b-2848-4499-bb65-dc8d8f391127' | System | 22 Sep 2020 22:35:31 |
| User entered 'No (N)' | System | 22 Sep 2020 22:35:31 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:35:11', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c946c9b-2848-4499-bb65-dc8d8f391127' | System | 22 Sep 2020 22:35:31 |
| User entered 'No (N)' | System | 22 Sep 2020 22:35:31 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:35:15', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c946c9b-2848-4499-bb65-dc8d8f391127' | System | 22 Sep 2020 22:35:31 |
| User entered 'None (1)' | System | 22 Sep 2020 22:35:31 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:35:27', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c946c9b-2848-4499-bb65-dc8d8f391127' | System | 22 Sep 2020 22:35:31 |
| User entered '22 Sep 2020 17:35' | System | 22 Sep 2020 22:35:31 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 12:00' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 11:59' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 16:09:13 |
| User entered 'Day 7' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:17:32', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '245524de-91d6-4b2e-b813-fb83a9bcdef2' | System | 24 Sep 2020 11:17:58 |
| User entered 'None (1)' | System | 24 Sep 2020 11:17:58 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:29

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:17:39', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '245524de-91d6-4b2e-b813-fb83a9bcdef2' | System | 24 Sep 2020 11:17:58 |
| User entered 'No (N)' | System | 24 Sep 2020 11:17:58 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:17:42', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '245524de-91d6-4b2e-b813-fb83a9bcdef2' | System | 24 Sep 2020 11:17:58 |
| User entered 'No (N)' | System | 24 Sep 2020 11:17:58 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:29

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:17:46', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '245524de-91d6-4b2e-b813-fb83a9bcdef2' | System | 24 Sep 2020 11:17:58 |
| User entered 'None (1)' | System | 24 Sep 2020 11:17:58 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:29

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:17:55', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '245524de-91d6-4b2e-b813-fb83a9bcdef2' | System | 24 Sep 2020 11:17:58 |
| User entered '24 Sep 2020 06:17' | System | 24 Sep 2020 11:17:58 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 12:00' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 11:59' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 16:09:13 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:26:58', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'cc9e9e78-2f02-4fb2-bd7a-21dfb815bdc1' | System | 17 Sep 2020 16:27:40 |
| User entered 'None (0)' | System | 17 Sep 2020 16:27:40 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:27:03', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'cc9e9e78-2f02-4fb2-bd7a-21dfb815bdc1' | System | 17 Sep 2020 16:27:40 |
| User entered 'None (0)' | System | 17 Sep 2020 16:27:40 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:27:10', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'cc9e9e78-2f02-4fb2-bd7a-21dfb815bdc1' | System | 17 Sep 2020 16:27:40 |
| User entered 'None (0)' | System | 17 Sep 2020 16:27:40 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:27:20', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'cc9e9e78-2f02-4fb2-bd7a-21dfb815bdc1' | System | 17 Sep 2020 16:27:40 |
| User entered 'None (0)' | System | 17 Sep 2020 16:27:40 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:27:23', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'cc9e9e78-2f02-4fb2-bd7a-21dfb815bdc1' | System | 17 Sep 2020 16:27:40 |
| User entered 'None (0)' | System | 17 Sep 2020 16:27:40 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:27:26', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'cc9e9e78-2f02-4fb2-bd7a-21dfb815bdc1' | System | 17 Sep 2020 16:27:40 |
| User entered 'None (0)' | System | 17 Sep 2020 16:27:40 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:27:31', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'cc9e9e78-2f02-4fb2-bd7a-21dfb815bdc1' | System | 17 Sep 2020 16:27:40 |
| User entered 'No (N)' | System | 17 Sep 2020 16:27:40 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:27:38', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'cc9e9e78-2f02-4fb2-bd7a-21dfb815bdc1' | System | 17 Sep 2020 16:27:40 |
| User entered '17 Sep 2020 11:27' | System | 17 Sep 2020 16:27:40 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 11:09' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 13:39' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 16:09:13 |
| User entered 'Day 1, after vaccination (at home)' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:45:22', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0651cac7-3977-49fb-ab83-c2e89ffe5343' | System | 17 Sep 2020 20:46:10 |
| User entered 'None (0)' | System | 17 Sep 2020 20:46:10 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:45:25', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0651cac7-3977-49fb-ab83-c2e89ffe5343' | System | 17 Sep 2020 20:46:10 |
| User entered 'None (0)' | System | 17 Sep 2020 20:46:10 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:45:30', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0651cac7-3977-49fb-ab83-c2e89ffe5343' | System | 17 Sep 2020 20:46:10 |
| User entered 'None (0)' | System | 17 Sep 2020 20:46:10 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:45:35', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0651cac7-3977-49fb-ab83-c2e89ffe5343' | System | 17 Sep 2020 20:46:10 |
| User entered 'None (0)' | System | 17 Sep 2020 20:46:10 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:45:38', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0651cac7-3977-49fb-ab83-c2e89ffe5343' | System | 17 Sep 2020 20:46:10 |
| User entered 'None (0)' | System | 17 Sep 2020 20:46:10 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:45:41', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0651cac7-3977-49fb-ab83-c2e89ffe5343' | System | 17 Sep 2020 20:46:10 |
| User entered 'None (0)' | System | 17 Sep 2020 20:46:10 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:45:45', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0651cac7-3977-49fb-ab83-c2e89ffe5343' | System | 17 Sep 2020 20:46:10 |
| User entered 'No (N)' | System | 17 Sep 2020 20:46:10 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:46:07', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0651cac7-3977-49fb-ab83-c2e89ffe5343' | System | 17 Sep 2020 20:46:10 |
| User entered '17 Sep 2020 15:46' | System | 17 Sep 2020 20:46:10 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 14:34' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 11:59' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 16:09:13 |
| User entered 'Day 2' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:21:44', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd9fe13c0-315e-46be-abc0-d2b8811a25c3' | System | 18 Sep 2020 21:22:27 |
| User entered 'None (0)' | System | 18 Sep 2020 21:22:27 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:21:48', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd9fe13c0-315e-46be-abc0-d2b8811a25c3' | System | 18 Sep 2020 21:22:27 |
| User entered 'None (0)' | System | 18 Sep 2020 21:22:27 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:21:52', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd9fe13c0-315e-46be-abc0-d2b8811a25c3' | System | 18 Sep 2020 21:22:27 |
| User entered 'None (0)' | System | 18 Sep 2020 21:22:27 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:21:56', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd9fe13c0-315e-46be-abc0-d2b8811a25c3' | System | 18 Sep 2020 21:22:27 |
| User entered 'None (0)' | System | 18 Sep 2020 21:22:27 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:21:59', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd9fe13c0-315e-46be-abc0-d2b8811a25c3' | System | 18 Sep 2020 21:22:27 |
| User entered 'None (0)' | System | 18 Sep 2020 21:22:27 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:22:02', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd9fe13c0-315e-46be-abc0-d2b8811a25c3' | System | 18 Sep 2020 21:22:27 |
| User entered 'None (0)' | System | 18 Sep 2020 21:22:27 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:22:08', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd9fe13c0-315e-46be-abc0-d2b8811a25c3' | System | 18 Sep 2020 21:22:27 |
| User entered 'No (N)' | System | 18 Sep 2020 21:22:27 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:22:23', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd9fe13c0-315e-46be-abc0-d2b8811a25c3' | System | 18 Sep 2020 21:22:27 |
| User entered '18 Sep 2020 16:22' | System | 18 Sep 2020 21:22:27 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 12:00' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 11:59' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 16:09:13 |
| User entered 'Day 3' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:04:01', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'b25028b2-fa31-455a-b798-c0e73dcbb273' | System | 20 Sep 2020 02:04:42 |
| User entered 'None (0)' | System | 20 Sep 2020 02:04:42 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:04:05', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'b25028b2-fa31-455a-b798-c0e73dcbb273' | System | 20 Sep 2020 02:04:42 |
| User entered 'None (0)' | System | 20 Sep 2020 02:04:42 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:04:09', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'b25028b2-fa31-455a-b798-c0e73dcbb273' | System | 20 Sep 2020 02:04:42 |
| User entered 'None (0)' | System | 20 Sep 2020 02:04:42 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:04:12', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'b25028b2-fa31-455a-b798-c0e73dcbb273' | System | 20 Sep 2020 02:04:42 |
| User entered 'None (0)' | System | 20 Sep 2020 02:04:42 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:04:15', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'b25028b2-fa31-455a-b798-c0e73dcbb273' | System | 20 Sep 2020 02:04:42 |
| User entered 'None (0)' | System | 20 Sep 2020 02:04:42 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:04:19', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'b25028b2-fa31-455a-b798-c0e73dcbb273' | System | 20 Sep 2020 02:04:42 |
| User entered 'None (0)' | System | 20 Sep 2020 02:04:42 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:04:25', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'b25028b2-fa31-455a-b798-c0e73dcbb273' | System | 20 Sep 2020 02:04:42 |
| User entered 'No (N)' | System | 20 Sep 2020 02:04:42 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:04:39', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'b25028b2-fa31-455a-b798-c0e73dcbb273' | System | 20 Sep 2020 02:04:42 |
| User entered '19 Sep 2020 21:04' | System | 20 Sep 2020 02:04:42 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 12:00' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 11:59' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 16:09:13 |
| User entered 'Day 4' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:55:25', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e72c2781-3854-4d4b-8112-ad37f417aa5c' | System | 20 Sep 2020 23:56:03 |
| User entered 'None (0)' | System | 20 Sep 2020 23:56:03 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:55:28', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e72c2781-3854-4d4b-8112-ad37f417aa5c' | System | 20 Sep 2020 23:56:03 |
| User entered 'None (0)' | System | 20 Sep 2020 23:56:03 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:55:33', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e72c2781-3854-4d4b-8112-ad37f417aa5c' | System | 20 Sep 2020 23:56:03 |
| User entered 'None (0)' | System | 20 Sep 2020 23:56:03 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:55:37', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e72c2781-3854-4d4b-8112-ad37f417aa5c' | System | 20 Sep 2020 23:56:03 |
| User entered 'None (0)' | System | 20 Sep 2020 23:56:03 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:55:41', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e72c2781-3854-4d4b-8112-ad37f417aa5c' | System | 20 Sep 2020 23:56:03 |
| User entered 'None (0)' | System | 20 Sep 2020 23:56:03 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:55:45', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e72c2781-3854-4d4b-8112-ad37f417aa5c' | System | 20 Sep 2020 23:56:03 |
| User entered 'None (0)' | System | 20 Sep 2020 23:56:03 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:55:50', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e72c2781-3854-4d4b-8112-ad37f417aa5c' | System | 20 Sep 2020 23:56:03 |
| User entered 'No (N)' | System | 20 Sep 2020 23:56:03 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:56:01', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e72c2781-3854-4d4b-8112-ad37f417aa5c' | System | 20 Sep 2020 23:56:03 |
| User entered '20 Sep 2020 18:56' | System | 20 Sep 2020 23:56:03 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 12:00' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 11:59' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 16:09:13 |
| User entered 'Day 5' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:21:18', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'c5adc57b-6045-4cba-af17-6c6ee44b4f59' | System | 21 Sep 2020 22:21:59 |
| User entered 'None (0)' | System | 21 Sep 2020 22:21:59 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:21:22', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'c5adc57b-6045-4cba-af17-6c6ee44b4f59' | System | 21 Sep 2020 22:21:59 |
| User entered 'None (0)' | System | 21 Sep 2020 22:21:59 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:21:26', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'c5adc57b-6045-4cba-af17-6c6ee44b4f59' | System | 21 Sep 2020 22:21:59 |
| User entered 'None (0)' | System | 21 Sep 2020 22:21:59 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:21:31', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'c5adc57b-6045-4cba-af17-6c6ee44b4f59' | System | 21 Sep 2020 22:21:59 |
| User entered 'None (0)' | System | 21 Sep 2020 22:21:59 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:21:34', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'c5adc57b-6045-4cba-af17-6c6ee44b4f59' | System | 21 Sep 2020 22:21:59 |
| User entered 'None (0)' | System | 21 Sep 2020 22:21:59 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:21:37', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'c5adc57b-6045-4cba-af17-6c6ee44b4f59' | System | 21 Sep 2020 22:21:59 |
| User entered 'None (0)' | System | 21 Sep 2020 22:21:59 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:21:42', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'c5adc57b-6045-4cba-af17-6c6ee44b4f59' | System | 21 Sep 2020 22:21:59 |
| User entered 'No (N)' | System | 21 Sep 2020 22:21:59 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:21:56', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'c5adc57b-6045-4cba-af17-6c6ee44b4f59' | System | 21 Sep 2020 22:21:59 |
| User entered '21 Sep 2020 17:21' | System | 21 Sep 2020 22:21:59 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 12:00' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 11:59' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 16:09:13 |
| User entered 'Day 6' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:35:40', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e7ef4493-2ea2-422b-b23f-d284b74b8aa1' | System | 22 Sep 2020 22:36:21 |
| User entered 'None (0)' | System | 22 Sep 2020 22:36:21 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:35:43', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e7ef4493-2ea2-422b-b23f-d284b74b8aa1' | System | 22 Sep 2020 22:36:21 |
| User entered 'None (0)' | System | 22 Sep 2020 22:36:21 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:35:50', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e7ef4493-2ea2-422b-b23f-d284b74b8aa1' | System | 22 Sep 2020 22:36:21 |
| User entered 'None (0)' | System | 22 Sep 2020 22:36:21 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:35:56', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e7ef4493-2ea2-422b-b23f-d284b74b8aa1' | System | 22 Sep 2020 22:36:21 |
| User entered 'None (0)' | System | 22 Sep 2020 22:36:21 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:36:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e7ef4493-2ea2-422b-b23f-d284b74b8aa1' | System | 22 Sep 2020 22:36:21 |
| User entered 'None (0)' | System | 22 Sep 2020 22:36:21 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:36:03', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e7ef4493-2ea2-422b-b23f-d284b74b8aa1' | System | 22 Sep 2020 22:36:21 |
| User entered 'None (0)' | System | 22 Sep 2020 22:36:21 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:36:09', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e7ef4493-2ea2-422b-b23f-d284b74b8aa1' | System | 22 Sep 2020 22:36:21 |
| User entered 'No (N)' | System | 22 Sep 2020 22:36:21 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:36:20', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e7ef4493-2ea2-422b-b23f-d284b74b8aa1' | System | 22 Sep 2020 22:36:21 |
| User entered '22 Sep 2020 17:36' | System | 22 Sep 2020 22:36:21 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 12:00' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 11:59' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 16:09:13 |
| User entered 'Day 7' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:18:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9c03fe36-6f3c-4c9c-8d39-9edefc395e00' | System | 24 Sep 2020 11:18:30 |
| User entered 'None (0)' | System | 24 Sep 2020 11:18:30 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:18:03', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9c03fe36-6f3c-4c9c-8d39-9edefc395e00' | System | 24 Sep 2020 11:18:30 |
| User entered 'None (0)' | System | 24 Sep 2020 11:18:30 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:18:06', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9c03fe36-6f3c-4c9c-8d39-9edefc395e00' | System | 24 Sep 2020 11:18:30 |
| User entered 'None (0)' | System | 24 Sep 2020 11:18:30 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:18:09', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9c03fe36-6f3c-4c9c-8d39-9edefc395e00' | System | 24 Sep 2020 11:18:30 |
| User entered 'None (0)' | System | 24 Sep 2020 11:18:30 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:18:12', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9c03fe36-6f3c-4c9c-8d39-9edefc395e00' | System | 24 Sep 2020 11:18:30 |
| User entered 'None (0)' | System | 24 Sep 2020 11:18:30 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:18:14', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9c03fe36-6f3c-4c9c-8d39-9edefc395e00' | System | 24 Sep 2020 11:18:30 |
| User entered 'None (0)' | System | 24 Sep 2020 11:18:30 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:18:18', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9c03fe36-6f3c-4c9c-8d39-9edefc395e00' | System | 24 Sep 2020 11:18:30 |
| User entered 'No (N)' | System | 24 Sep 2020 11:18:30 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:18:29', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9c03fe36-6f3c-4c9c-8d39-9edefc395e00' | System | 24 Sep 2020 11:18:30 |
| User entered '24 Sep 2020 06:18' | System | 24 Sep 2020 11:18:30 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 12:00' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:29

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 11:59' | System | 17 Sep 2020 16:09:13 |

US3292236

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:47:54 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 28 Sep 2020 15:41:55 |

US3292236

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:47:54 |
| User entered '25 Sep 2020' | Kristy Trevino (b) (4) (b) (4) | 28 Sep 2020 15:41:55 |

US3292236

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:47:54 |
| User entered 'Contact Made (CONTACT MADE)' | Kristy Trevino (b) (4) (b) (4) | 28 Sep 2020 15:41:55 |

US3292236

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:47:54 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 28 Sep 2020 15:41:55 |

US3292236

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:48:01 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 28 Sep 2020 15:47:58 |

US3292236

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 28 Sep 2020 15:47:58 |

US3292236

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:48:36 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 02 Oct 2020 16:55:52 |

US3292236

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:48:36 |
| User entered '2 Oct 2020' | Kristy Trevino (b) (4) (b) (4) | 02 Oct 2020 16:55:52 |

US3292236

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:48:36 |
| User entered 'Contact Made (CONTACT MADE)' | Kristy Trevino (b) (4) (b) (4) | 02 Oct 2020 16:55:52 |

US3292236

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:48:36 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 02 Oct 2020 16:55:52 |

US3292236

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:48:42 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 02 Oct 2020 16:58:32 |

US3292236

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 02 Oct 2020 16:58:32 |

US3292236

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:52:20 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 09 Oct 2020 14:12:26 |

US3292236

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:52:20 |
| User entered '9 Oct 2020' | (b) (4), (b) (6) | 09 Oct 2020 14:12:26 |

US3292236

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:52:20 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 09 Oct 2020 14:12:26 |

US3292236

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:29

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:52:20 |
| User entered empty. | (b) (4), (b) (6) | 09 Oct 2020 14:12:26 |

US3292236

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:52:26 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 09 Oct 2020 14:12:31 |

US3292236

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 09 Oct 2020 14:12:31 |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:29

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|------------------------|----------------------------|----------------------|
| User entered 'Yes (Y)' | Victoria Hernandez (b) (4) | 05 Nov 2020 19:44:41 |
| | (b) (4) | |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:29

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| User entered '15 Oct 2020' | Victoria Hernandez (b) (4) | 05 Nov 2020 19:44:41 |
| | (b) (4) | |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Victoria Hernandez (b) (4) | 05 Nov 2020 19:44:41 |
| | (b) (4) | |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:29

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'VISIT3' | System | 05 Nov 2020 19:44:41 |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

Were vital signs assessed?

| Audit | User | Time (GMT) |
|------------------------|----------------------------|----------------------|
| User entered 'Yes (Y)' | Victoria Hernandez (b) (4) | 05 Nov 2020 19:45:21 |
| | (b) (4) | |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| User entered '15 Oct 2020' | Victoria Hernandez (b) (4) | 05 Nov 2020 19:45:21 |
| | (b) (4) | |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------|----------------------------|----------------------|
| User entered '11:00' | Victoria Hernandez (b) (4) | 05 Nov 2020 19:45:21 |
| | (b) (4) | |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '15 Oct 2020 11:00' | System | 05 Nov 2020 19:45:21 |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------|----------------------------|----------------------|
| User entered '36.7' C | Victoria Hernandez (b) (4) | 05 Nov 2020 19:45:21 |
| | (b) (4) | |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| User entered 'Oral (Oral)' | Victoria Hernandez (b) (4) | 05 Nov 2020 19:45:21 |
| | (b) (4) | |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| User entered empty. | Victoria Hernandez (b) (4) | 05 Nov 2020 19:45:21 |
| | (b) (4) | |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| User entered '74' | Victoria Hernandez (b) (4) | 05 Nov 2020 19:45:21 |
| | (b) (4) | |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 05 Nov 2020 19:45:21 |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| User entered '16' | Victoria Hernandez (b) (4) | 05 Nov 2020 19:45:21 |
| | (b) (4) | |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 05 Nov 2020 19:45:21 |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------|----------------------------|----------------------|
| User entered '103' | Victoria Hernandez (b) (4) | 05 Nov 2020 19:45:21 |
| | (b) (4) | |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 05 Nov 2020 19:45:21 |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|----------------------------|------------------------------|
| User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | (b) (4), (b) (6) | 10 Nov 2020 20:45:55 |
| Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System). | Victoria Hernandez (b) (4) | (b) (4) 05 Nov 2020 19:45:31 |
| User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | | 05 Nov 2020 19:45:21 |
| User entered '59' | Victoria Hernandez (b) (4) | (b) (4) 05 Nov 2020 19:45:21 |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:29

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 05 Nov 2020 19:45:21 |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:29

Was the physical examination performed?

| Audit | User | Time (GMT) |
|-----------------------|----------------------------|----------------------|
| User entered 'No (N)' | Victoria Hernandez (b) (4) | 05 Nov 2020 19:45:43 |
| | (b) (4) | |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:29

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| User entered empty. | Victoria Hernandez (b) (4) | 05 Nov 2020 19:45:43 |
| | (b) (4) | |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:29

Was the sample collected?

| Audit | User | Time (GMT) |
|------------------------|----------------------------|----------------------|
| User entered 'Yes (Y)' | Victoria Hernandez (b) (4) | 05 Nov 2020 19:46:05 |
| | (b) (4) | |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:29

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| User entered '15 Oct 2020' | Victoria Hernandez (b) (4) | 05 Nov 2020 19:46:05 |
| | (b) (4) | |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:29

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|----------------------|----------------------------|----------------------|
| User entered '11:10' | Victoria Hernandez (b) (4) | 05 Nov 2020 19:46:05 |
| | (b) (4) | |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:29

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '15 Oct 2020 11:10' | System | 05 Nov 2020 19:46:05 |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|----------------------------|----------------------|
| User entered 'Yes (Y)' | Victoria Hernandez (b) (4) | 05 Nov 2020 19:46:11 |
| | (b) (4) | |

US3292236

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:29

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Nov 2020 19:46:11 |

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 64' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-10-20T05:33:03', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '3dd4520e-daf7-4991-82b6-ee962d1f9c22' | System | 20 Oct 2020 10:33:31 |
| User entered 'No (N)' | System | 20 Oct 2020 10:33:31 |

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-10-20T05:33:09', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '3dd4520e-daf7-4991-82b6-ee962d1f9c22' | System | 20 Oct 2020 10:33:31 |
| User entered 'No (N)' | System | 20 Oct 2020 10:33:31 |

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-10-20T05:33:28', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '3dd4520e-daf7-4991-82b6-ee962d1f9c22' User entered '20 Oct 2020 05:33:28' | System | 20 Oct 2020 10:33:31 |
| | System | 20 Oct 2020 10:33:31 |

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered '20 Oct 2020 00:01' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered '24 Oct 2020 23:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 71' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-10-28T09:18:41', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '07cf0f05-4287-4513-9da8-073aa1674126' | System | 28 Oct 2020 14:19:01 |
| User entered 'No (N)' | System | 28 Oct 2020 14:19:01 |

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-10-28T09:18:45', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '07cf0f05-4287-4513-9da8-073aa1674126' | System | 28 Oct 2020 14:19:01 |
| User entered 'No (N)' | System | 28 Oct 2020 14:19:01 |

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-10-28T09:18:59', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '07cf0f05-4287-4513-9da8-073aa1674126' User entered '28 Oct 2020 09:18:59' | System | 28 Oct 2020 14:19:01 |
| | System | 28 Oct 2020 14:19:01 |

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered '27 Oct 2020 00:01' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered '31 Oct 2020 23:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 78' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-11-04T10:40:46', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '5a10a23c-8e68-473b-a6ab-d110d643fe43' | System | 04 Nov 2020 16:41:01 |
| User entered 'No (N)' | System | 04 Nov 2020 16:41:01 |

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-11-04T10:40:52', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '5a10a23c-8e68-473b-a6ab-d110d643fe43' | System | 04 Nov 2020 16:41:01 |
| User entered 'No (N)' | System | 04 Nov 2020 16:41:01 |

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-11-04T10:40:58', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '5a10a23c-8e68-473b-a6ab-d110d643fe43' User entered '04 Nov 2020 10:40:58' | System | 04 Nov 2020 16:41:01 |
| | System | 04 Nov 2020 16:41:01 |

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered '03 Nov 2020 00:01' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered '07 Nov 2020 23:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered 'Day 92' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-11-17T12:58:21', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '2f1cfc39-35f7-4169-ba9f-e6780b344d33' | System | 17 Nov 2020 18:58:36 |
| User entered 'No (N)' | System | 17 Nov 2020 18:58:36 |

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-11-17T12:58:24', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '2f1cfc39-35f7-4169-ba9f-e6780b344d33' | System | 17 Nov 2020 18:58:36 |
| User entered 'No (N)' | System | 17 Nov 2020 18:58:36 |

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-11-17T12:58:31', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '2f1cfc39-35f7-4169-ba9f-e6780b344d33' User entered '17 Nov 2020 12:58:31' | System | 17 Nov 2020 18:58:36 |
| | System | 17 Nov 2020 18:58:36 |

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered '17 Nov 2020 00:01' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 15:25:41 |
| User entered '21 Nov 2020 23:59' | System | 20 Aug 2020 15:25:41 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 61' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '17 Oct 2020 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '21 Oct 2020 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 68' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '24 Oct 2020 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '28 Oct 2020 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 75' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '31 Oct 2020 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '04 Nov 2020 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 82' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '07 Nov 2020 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '11 Nov 2020 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 89' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '14 Nov 2020 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '18 Nov 2020 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-11-22T09:47:12', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'da408f1c-365c-44f7-9170-36022859265c' User entered 'No (N)' | System | 22 Nov 2020 15:47:29 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-11-22T09:47:17', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'da408f1c-365c-44f7-9170-36022859265c' | System | 22 Nov 2020 15:47:29 |
| User entered 'No (N)' | System | 22 Nov 2020 15:47:29 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-11-22T09:47:24', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'da408f1c-365c-44f7-9170-36022859265c' User entered '22 Nov 2020 09:47:24' | System | 22 Nov 2020 15:47:29 |
| | System | 22 Nov 2020 15:47:29 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '21 Nov 2020 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '25 Nov 2020 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '28 Nov 2020 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '02 Dec 2020 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '05 Dec 2020 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '09 Dec 2020 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '12 Dec 2020 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '16 Dec 2020 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '19 Dec 2020 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '23 Dec 2020 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '26 Dec 2020 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '30 Dec 2020 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '02 Jan 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '06 Jan 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '09 Jan 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '13 Jan 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '16 Jan 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '20 Jan 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '23 Jan 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '27 Jan 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '30 Jan 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '03 Feb 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '06 Feb 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '10 Feb 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '13 Feb 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '17 Feb 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '20 Feb 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '24 Feb 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '27 Feb 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '03 Mar 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '06 Mar 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '10 Mar 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '13 Mar 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '17 Mar 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '20 Mar 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '24 Mar 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '27 Mar 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '31 Mar 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '03 Apr 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '07 Apr 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '10 Apr 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '14 Apr 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '17 Apr 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '21 Apr 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '24 Apr 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '28 Apr 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '01 May 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '05 May 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '08 May 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '12 May 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '15 May 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '19 May 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '22 May 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '26 May 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '29 May 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '02 Jun 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '05 Jun 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '09 Jun 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '12 Jun 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '16 Jun 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '19 Jun 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '23 Jun 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '26 Jun 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '30 Jun 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '03 Jul 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '07 Jul 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '10 Jul 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '14 Jul 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '17 Jul 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '21 Jul 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '24 Jul 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '28 Jul 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '31 Jul 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '04 Aug 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '07 Aug 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '11 Aug 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '14 Aug 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '18 Aug 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '21 Aug 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '25 Aug 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '28 Aug 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '01 Sep 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '04 Sep 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '08 Sep 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '11 Sep 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '15 Sep 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '18 Sep 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '22 Sep 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '25 Sep 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '29 Sep 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '02 Oct 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '06 Oct 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '09 Oct 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '13 Oct 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '16 Oct 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '20 Oct 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '23 Oct 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '27 Oct 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '30 Oct 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '03 Nov 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '06 Nov 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '10 Nov 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '13 Nov 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '17 Nov 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '20 Nov 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '24 Nov 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '27 Nov 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '01 Dec 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '04 Dec 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '08 Dec 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '11 Dec 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '15 Dec 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '18 Dec 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '22 Dec 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '25 Dec 2021 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '29 Dec 2021 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '01 Jan 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '05 Jan 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '08 Jan 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '12 Jan 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '15 Jan 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '19 Jan 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '22 Jan 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '26 Jan 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '29 Jan 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '02 Feb 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '05 Feb 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '09 Feb 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '12 Feb 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '16 Feb 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '19 Feb 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '23 Feb 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '26 Feb 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '02 Mar 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '05 Mar 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '09 Mar 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '12 Mar 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '16 Mar 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '19 Mar 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '23 Mar 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '26 Mar 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '30 Mar 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '02 Apr 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '06 Apr 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '09 Apr 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '13 Apr 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '16 Apr 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '20 Apr 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '23 Apr 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '27 Apr 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '30 Apr 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '04 May 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '07 May 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '11 May 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '14 May 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '18 May 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '21 May 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '25 May 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '28 May 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '01 Jun 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '04 Jun 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '08 Jun 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '11 Jun 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '15 Jun 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '18 Jun 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '22 Jun 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '25 Jun 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '29 Jun 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '02 Jul 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '06 Jul 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '09 Jul 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '13 Jul 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '16 Jul 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '20 Jul 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '23 Jul 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '27 Jul 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '30 Jul 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '03 Aug 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '06 Aug 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '10 Aug 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '13 Aug 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '17 Aug 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '20 Aug 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '24 Aug 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '27 Aug 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '31 Aug 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '03 Sep 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '07 Sep 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '10 Sep 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '14 Sep 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '17 Sep 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '21 Sep 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '24 Sep 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '28 Sep 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '01 Oct 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '05 Oct 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '08 Oct 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '12 Oct 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '15 Oct 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '19 Oct 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '22 Oct 2022 00:01' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:29

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:37:05 |
| Amendment Manager: User entered '26 Oct 2022 23:59' | System | 19 Nov 2020 23:37:05 |

US3292236

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:56:29

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| Query 'Diagnosis of Vertigo was listed on Discharge Summary. Please confirm and consider updating AE log' answered with 'Vertigo was added' (Site from CRA). | Antonio Gutierrez (b) (4) | 24 Nov 2020 22:13:41 |
| User opened query 'The subject reported nausea secondary to a migraine on the Day 43 Safety Call. Please consider adding as an AE if appropriate.' (Site from CRA). | (b) (4), (b) (6) | 06 Nov 2020 16:51:43 |
| User opened query 'Diagnosis of Nausea was listed on Discharge Summary. Please confirm and consider updating AE log.' (Site from CRA). | (b) (4), (b) (6) | 23 Oct 2020 19:55:11 |
| User opened query 'Diagnosis of Vertigo was listed on Discharge Summary. Please confirm and consider updating AE log' (Site from CRA). | (b) (4), (b) (6) | 23 Oct 2020 19:54:53 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:01 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 09 Sep 2020 13:44:55 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[AEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:25:35 |
| User entered 'USA-US072-2020-mRNA-1273-P301000001' | System | 10 Sep 2020 17:22:57 |
| User entered 'New' | (b) (4), (b) (6) | 10 Sep 2020 17:22:57 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User closed query 'PV Query: Please confirm if the reported "possible fibromuscular dysplasia" was considered an SAE. If yes, please provide missing seriousness criteria as soon as possible.' (Site from Safety). | (b) (4), (b) (6) | 22 Sep 2020 14:48:42 |
| User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. Please update as applicable.' (Site from Safety). | (b) (4), (b) (6) | 22 Sep 2020 14:48:33 |
| User closed query 'PV Query: Please confirm the sex of the subject as Medical History of uterine fibroids and hysterectomy does not coincide with a male subject and reconcile accordingly.' (Site from Safety). | (b) (4), (b) (6) | 22 Sep 2020 14:47:00 |
| User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Non-site specific necrosis and vascular insufficiency NEC, PT: Fibromuscular dysplasia, LLT: Fibromuscular dysplasia - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Sep 2020 22:56:46 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Sep 2020 22:56:46 |
| Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. Please update as applicable.' answered with 'updated' (Site from Safety). | Kevin Martinez (b) (4) (b) (4) | 21 Sep 2020 22:56:24 |
| Query 'PV Query: Please confirm if the reported "possible fibromuscular dysplasia" was considered an SAE. If yes, please provide missing seriousness criteria as soon as possible.' answered with 'updated' (Site from Safety). | Kevin Martinez (b) (4) (b) (4) | 21 Sep 2020 22:56:18 |
| Data point term sent to Coder | System | 21 Sep 2020 22:55:43 |
| Coding entries removed. | Kevin Martinez (b) (4) (b) (4) | 21 Sep 2020 22:54:48 |
| User entered 'Fibromuscular Dysplasia' reason for change: Data Entry Error | Kevin Martinez (b) (4) (b) (4) | 21 Sep 2020 22:54:48 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Query 'PV Query: Please confirm the sex of the subject as Medical History of uterine fibroids and hysterectomy does not coincide with a male subject and reconcile accordingly.' answered with 'UPDATED' (Site from Safety). | Victoria Hernandez (b) (4) | 21 Sep 2020 22:07:21 |
| User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. Please update as applicable.' (Site from Safety). | (b) (4), (b) (6) | 16 Sep 2020 19:40:06 |
| User opened query 'PV Query: Please confirm if the reported "possible fibromuscular dysplasia" was considered an SAE. If yes, please provide missing seriousness criteria as soon as possible.' (Site from Safety). | (b) (4), (b) (6) | 16 Sep 2020 19:39:54 |
| User opened query 'PV Query: Please confirm the sex of the subject as Medical History of uterine fibroids and hysterectomy does not coincide with a male subject and reconcile accordingly.' (Site from Safety). | (b) (4), (b) (6) | 16 Sep 2020 19:38:26 |
| User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 11 Sep 2020 13:54:39 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 11 Sep 2020 13:54:39 |
| Data point term sent to Coder | System | 09 Sep 2020 14:17:25 |
| User entered 'Dizziness, nausea secondary to the dizziness.' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 15:42:32 |
| User closed query 'Start Date in source is listed as 04SEP2020. Please reconcile.' (Site from CRA). | (b) (4), (b) (6) | 06 Nov 2020 15:42:18 |
| Query 'Start Date in source is listed as 04SEP2020. Please reconcile.' answered with 'updated' (Site from CRA). | Antonio Gutierrez (b) (4) | 04 Nov 2020 16:19:20 |
| User entered '4 Sep 2020' reason for change: Per Query Resolution | Antonio Gutierrez (b) (4) | 04 Nov 2020 16:19:13 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 18:19:00 |
| User opened query 'Start Date in source is listed as 04SEP2020. Please reconcile.' (Site from CRA). | (b) (4), (b) (6) | 21 Oct 2020 18:18:48 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User entered '3 Sep 2020' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 15:42:34 |
| User closed query 'Per source, start time is 7:30. Please confirm/update.' (Site from CRA). | (b) (4), (b) (6) | 06 Nov 2020 15:42:30 |
| Query 'Per source, start time is 7:30. Please confirm/update.' answered with 'no time required as per system query that states " Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.'" (Site from CRA). | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:04:10 |
| User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System). | System | 05 Nov 2020 23:03:42 |
| User entered empty; reason for change Per Query Resolution | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:03:42 |
| User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System). | System | 05 Nov 2020 23:02:50 |
| User entered '07:30' reason for change: Per Query Resolution | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:02:50 |
| User opened query 'Per source, start time is 7:30. Please confirm/update.' (Site from CRA). | (b) (4), (b) (6) | 21 Oct 2020 18:21:46 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 18:19:02 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User entered empty. | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 23:03:42 |
| User entered '4 Sep 2020 07:30' | System | 05 Nov 2020 23:02:50 |
| User entered empty. | System | 09 Sep 2020 14:17:25 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User entered '5 Sep 2020' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:07:59 |
| User closed query 'End time per source was 1300. Please update/confirm.' (Site from CRA). | (b) (4), (b) (6) | 06 Nov 2020 16:07:55 |
| User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System). | System | 05 Nov 2020 23:05:15 |
| User entered empty; reason for change Per Query Resolution | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:05:15 |
| Query 'End time per source was 1300. Please update/confirm.' answered with 'No time required as per system query that states "End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time."' (Site from CRA). | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:04:58 |
| User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System). | System | 05 Nov 2020 23:02:50 |
| User entered '13:00' reason for change: Per Query Resolution | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:02:50 |
| User opened query 'End time per source was 1300. Please update/confirm.' (Site from CRA). | (b) (4), (b) (6) | 21 Oct 2020 18:22:16 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 18:21:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User entered empty. | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 23:05:15 |
| User entered '5 Sep 2020 13:00' | System | 05 Nov 2020 23:02:50 |
| User entered empty. | System | 09 Sep 2020 14:17:25 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Severity](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User closed query 'PV Query: The event intensity is "Grade 4" for this event of dizziness, nausea secondary to the dizziness. Per the vaccine grading (Grade 4=potential life-threatening). Please include "life-threatening" as an additional seriousness criterion or please reassess the event intensity grade, and update as applicable.' (Site from Safety). | (b) (4), (b) (6) | 22 Sep 2020 14:48:48 |
| Query 'PV Query: The event intensity is "Grade 4" for this event of dizziness, nausea secondary to the dizziness. Per the vaccine grading (Grade 4=potential life-threatening). Please include "life-threatening" as an additional seriousness criterion or please reassess the event intensity grade, and update as applicable.' answered with 'entry error, updated' (Site from Safety). | Kevin Martinez (b) (4) | 21 Sep 2020 22:54:34 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error | Kevin Martinez (b) (4) | 21 Sep 2020 22:41:55 |
| User opened query 'PV Query: The event intensity is "Grade 4" for this event of dizziness, nausea secondary to the dizziness. Per the vaccine grading (Grade 4=potential life-threatening). Please include "life-threatening" as an additional seriousness criterion or please reassess the event intensity grade, and update as applicable.' (Site from Safety). | (b) (4), (b) (6) | 16 Sep 2020 19:40:36 |
| User entered 'Grade 4 (Grade 4)' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Death](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User entered '0' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Life threatening](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User entered '0' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User closed query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' (Site from Safety). | (b) (4), (b) (6) | 22 Sep 2020 14:48:55 |
| Query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' answered with 'patient was admitted from 04Sep2020 till 05Sep2020' (Site from Safety). | Kevin Martinez (b) (4) | 21 Sep 2020 22:49:16 |
| User opened query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' (Site from Safety). | (b) (4), (b) (6) | 16 Sep 2020 19:40:22 |
| User entered 'I' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User entered '4 Sep 2020' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety). | (b) (4), (b) (6) | 25 Sep 2020 16:48:27 |
| Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Discharge summary sent today, 24SEP2020 by AG.' (Site from Safety). | Antonio Gutierrez (b) (4) | 24 Sep 2020 22:03:44 |
| User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety). | (b) (4), (b) (6) | 16 Sep 2020 19:38:41 |
| User entered '5 Sep 2020' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User entered empty. | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User entered '0' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User entered '0' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User entered '0' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User entered 'Not Related (NOT RELATED)' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User entered 'Not Related (NOT RELATED)' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User entered 'None (NONE)' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

None

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). DataPoint Un-verified. | System | 24 Nov 2020 22:24:40 |
| | Antonio Gutierrez (b) (4) | 24 Nov 2020 22:24:40 |
| User entered '1' reason for change: Per Query Resolution | Antonio Gutierrez (b) (4) | 24 Nov 2020 22:24:40 |
| User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). DataPoint Verified. | System | 24 Nov 2020 22:24:03 |
| | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User entered '0' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, MECLIZINE is indicated for "VERTIGO" and not for this AE. Please review and add a Con Medication as appropriate or update action taken' answered with 'updated' (Site from DM). | Antonio Gutierrez (b) (4) | 24 Nov 2020 22:21:06 |
| DataPoint Un-verified. | Antonio Gutierrez (b) (4) | 24 Nov 2020 22:20:54 |
| User entered '0' reason for change: Per Query Resolution | Antonio Gutierrez (b) (4) | 24 Nov 2020 22:20:54 |
| User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, MECLIZINE is indicated for "VERTIGO" and not for this AE. Please review and add a Con Medication as appropriate or update action taken' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 23:15:17 |
| User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). | (b) (4), (b) (6) | 09 Nov 2020 14:35:44 |
| Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Meclizine added' (Site from DM). | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:15:41 |
| User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). | (b) (4), (b) (6) | 01 Nov 2020 08:50:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| User closed query 'PV Query: Please confirm if Aimovig (prescribed on 21 Aug 2020) should be added as concomitant medication.' (Site from Safety). | (b) (4), (b) (6) | 22 Sep 2020 14:49:08 |
| User entered '1' reason for change: Data Entry Error | Kevin Martinez (b) (4) | 21 Sep 2020 22:39:14 |
| Query 'PV Query: Please confirm if Aimovig (prescribed on 21 Aug 2020) should be added as concomitant medication.' answered with 'updated in concomitant medication' (Site from Safety). | Kevin Martinez (b) (4) | 21 Sep 2020 22:38:47 |
| User opened query 'PV Query: Please confirm if Aimovig (prescribed on 21 Aug 2020) should be added as concomitant medication.' (Site from Safety). | (b) (4), (b) (6) | 16 Sep 2020 19:41:11 |
| User entered '0' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'updated as per query' (Site from DM). DataPoint Un-verified. | Antonio Gutierrez (b) (4) | 24 Nov 2020 22:24:50 |
| User entered '0' reason for change: Per Query Resolution | Antonio Gutierrez (b) (4) | 24 Nov 2020 22:24:03 |
| User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 23:17:28 |
| User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM). | (b) (4), (b) (6) | 09 Nov 2020 14:35:46 |
| User closed query 'MRA and MRI were mentioned in hospital discharge summary. Please consider updating Con Procedure page if found appropriate.' (Site from CRA). | (b) (4), (b) (6) | 06 Nov 2020 18:19:19 |
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 18:19:13 |
| Query 'MRA and MRI were mentioned in hospital discharge summary. Please consider updating Con Procedure page if found appropriate.' answered with 'will update' (Site from CRA). | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:51:33 |
| User entered '1' reason for change: New Information | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:51:14 |
| User opened query 'MRA and MRI were mentioned in hospital discharge summary. Please consider updating Con Procedure page if found appropriate.' (Site from CRA). | (b) (4), (b) (6) | 21 Oct 2020 18:39:45 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|--|---------------------------------------|--|
| Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'updated' (Site from DM). DataPoint Un-verified. | Victoria Hernandez (b) (4) (b) (4) | (b) (4) 13 Oct 2020 20:42:21 |
| User entered '0' reason for change: Data Entry Error | Victoria Hernandez (b) (4) (b) (4) | (b) (4) 13 Oct 2020 20:42:13 |
| User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM). DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 23:55:56 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'No medication treatments given during hospitalization.' (Site from Safety). | Kevin Martinez (b) (4) (b) (4) | 22 Sep 2020 14:49:14 21 Sep 2020 22:54:15 |

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Folder: Adverse Events

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[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6) | 16 Sep 2020 19:39:10 |
| User entered 'I' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Outcome](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User entered empty. | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Narrative](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Query 'Per DM CLR: SAE Narrative = PT STATES DOCTORS DID "EVERY TEST KNOWN TO MAN". Please confirm if these tests were followed up and verified. If yes, please ensure that these were captured in the appropriate eCRF. Otherwise, clarify.' answered with 'all tests based on medical records request have been reconciled. Diagnostic tests noted ' (Site from DM). | Antonio Gutierrez (b) (4) | 24 Nov 2020 22:28:50 |
| Query 'Per DM CLR: SAE Narrative = EMT GAVE PT SOMETHING FOR NAUSEA, THOUGH PT CANNOT RECALL WHAT IT WAS. Please confirm if this medication was followed up and verified. If yes, please ensure that this is captured in the appropriate eCRF. Otherwise, clarify.' answered with 'It was followed up, but medication is unknown' (Site from DM). | Antonio Gutierrez (b) (4) | 24 Nov 2020 22:28:01 |
| Query 'PV Query: Please clarify whether the subjected received the second IP administration.' answered with 'Second IP administration received 17SEP2020' (Site from Safety). | Antonio Gutierrez (b) (4) | 24 Nov 2020 22:27:31 |
| User opened query 'Per DM CLR: SAE Narrative = PT STATES DOCTORS DID "EVERY TEST KNOWN TO MAN". Please confirm if these tests were followed up and verified. If yes, please ensure that these were captured in the appropriate eCRF. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 23:12:23 |
| User opened query 'Per DM CLR: SAE Narrative = EMT GAVE PT SOMETHING FOR NAUSEA, THOUGH PT CANNOT RECALL WHAT IT WAS. Please confirm if this medication was followed up and verified. If yes, please ensure that this is captured in the appropriate eCRF. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 23:12:14 |
| User opened query 'PV Query: Please clarify whether the subjected received the second IP administration.' (Site from Safety). | (b) (4), (b) (6) | 13 Nov 2020 16:37:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:18:27 |
| User closed query 'Per AE log in source, recorded by date was 17SEP2020 and Date AE reported was 19SEP2020. Please reconcile.' (Site from CRA). | (b) (4), (b) (6) | 06 Nov 2020 16:18:23 |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Query 'Per AE log in source, recorded by date was 17SEP2020 and Date AE reported was 19SEP2020. Please reconcile.' answered with 'These dates are erroneous. Will correct as per documentation in electronic source documents' (Site from CRA). | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:36:40 |
| User opened query 'Per AE log in source, recorded by date was 17SEP2020 and Date AE reported was 19SEP2020. Please reconcile.' (Site from CRA). | (b) (4), (b) (6) | 21 Oct 2020 18:25:07 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 18:24:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 18:16:09 |
| User closed query 'PV Query: It was reported that the subject underwent an MRI, please provide test results and any other relevant laboratory and diagnostic test results (including Covid testing). Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 25 Sep 2020 16:48:33 |
| Query 'PV Query: It was reported that the subject underwent an MRI, please provide test results and any other relevant laboratory and diagnostic test results (including Covid testing). Please include units and reference ranges if applicable.' answered with 'Narrative has been updated with requested information' (Site from Safety). | Antonio Gutierrez (b) (4) | 24 Sep 2020 22:09:56 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Narrative](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User entered "THIS REPORT IS FOLLOWING PATIENT'S INITIAL REPORT TO STAFF ON THE MORNING OF 09SEP2020. PT RECEIVED FIRST IP INJECTION ON 20AUG2020. ON 21ST, PT HAD APPOINTMENT WITH DOCTOR FOR MIGRAINES. DOCTOR PRESCRIBED AIMOVIG, WHICH PT STARTED IMMEDIATELY. ON 03SEP, PT WAS "NOT FEELING NORMAL". SHE COULD NOT DESCRIBE HER SYMPTOMS, SIMPLY STATING SHE WAS NOT FEELING NORMAL. ON 04SEP PT STATES SHE WOKE UP TO THE ROOM SPINNING, SHE WAS EXPERIENCING NAUSEA, AND CALLED AN AMBULANCE. WHILE IN THE AMBULANCE, EMT GAVE PT SOMETHING FOR NAUSEA, THOUGH PT CANNOT RECALL WHAT IT WAS. WHILE IN THE ER, PT STATES DOCTORS DID "EVERY TEST KNOWN TO MAN", BUT COULD NOT FIND ANYTHING ABNORMAL. DOCTORS DECIDED TO CONDUCT MRI WITH CONTRAST. ACCORDING TO PATIENT, SHE WAS TOLD BY HER DOCTOR THAT SHE HAD "POSSIBLE FIBROMUSCULAR DYSPLASIA". AT THIS TIME, PT WAS UNABLE TO PROVIDE ANY FURTHER INFORMATION. WE WILL REQUEST MEDICAL RECORDS FROM HOSPITAL ASAP. UPDATE: Discharge summary sent to Safety 24SEP2020. States "MRI findings of beading in distal cervical arteries suggested possible fibromuscular dysplasia." D/c summary also states that patient is to follow up with Neurologist to discuss these findings. No further information or lab results given. COVID testing not mentioned. Please review report.' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 24 Sep 2020 22:09:47 |
| User opened query 'PV Query: It was reported that the subject underwent an MRI, please provide test results and any other relevant laboratory and diagnostic test results (including Covid testing). Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 16 Sep 2020 19:38:58 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Narrative](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| User entered 'This report is following patient's initial report to staff on the morning of 09SEP2020. PT RECEIVED FIRST IP INJECTION ON 20AUG2020. ON 21ST, PT HAD APPOINTMENT WITH DOCTOR FOR MIGRAINES. DOCTOR PRESCRIBED AIMOVIG, WHICH PT STARTED IMMEDIATELY. ON 03SEP, PT WAS "NOT FEELING NORMAL". SHE COULD NOT DESCRIBE HER SYMPTOMS, SIMPLY STATING SHE WAS NOT FEELING NORMAL. ON 04SEP PT STATES SHE WOKE UP TO THE ROOM SPINNING, SHE WAS EXPERIENCING NAUSEA, AND CALLED AN AMBULANCE. WHILE IN THE AMBULANCE, EMT GAVE PT SOMETHING FOR NAUSEA, THOUGH PT CANNOT RECALL WHAT IT WAS. WHILE IN THE ER, PT STATES DOCTORS DID "EVERY TEST KNOWN TO MAN", BUT COULD NOT FIND ANYTHING ABNORMAL. DOCTORS DECIDED TO CONDUCT MRI WITH CONTRAST. ACCORDING TO PATIENT, SHE WAS TOLD BY HER DOCTOR THAT SHE HAD "POSSIBLE FIBROMUSCULAR DYSPLASIA". AT THIS TIME, PT WAS UNABLE TO PROVIDE ANY FURTHER INFORMATION. WE WILL REQUEST MEDICAL RECORDS FROM HOSPITAL ASAP.' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 09 Sep 2020 15:51:56 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Narrative](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| User entered 'Pt received first IP injection on 20AUG2020. On 21st, pt had appointment with doctor for migraines. Doctor prescribed AIMOVIG, which pt started immediately. On 03SEP, pt was "not feeling normal". She could not describe her symptoms, simply stating she was not feeling normal. On 04SEP pt states she woke up to the room spinning, she was experiencing nausea, and called an ambulance. While in the ambulance, EMT gave pt something for nausea, though pt cannot recall what it was. While in the ER, pt states doctors did "every test known to man", but could not find anything abnormal. Doctors decided to conduct MRI with contrast. According to patient, she was told by her doctor that she had "possible fibromuscular dysplasia". At this time, pt was unable to provide any further information. We will request medical records from hospital asap.' | Antonio Gutierrez (b) (4) | 09 Sep 2020 14:17:25 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 09 Sep 2020 14:17:25 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 09 Sep 2020 14:17:25 |

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 09 Sep 2020 14:17:25 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Vertigo, LLT: Vertigo - version MedDRA\\23.0. | Coder Import (b) (4) | 10 Nov 2020 00:17:39 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 10 Nov 2020 00:17:39 |
| Data point term sent to Coder | System | 10 Nov 2020 00:17:15 |
| User entered 'Vertigo' | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------|----------------------|
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------|----------------------|
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

Start date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User entered '3 Sep 2020' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 24 Nov 2020 22:32:33 |
| User entered '3 Nov 2020' | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| User entered empty. | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

If not Ongoing, end date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| User entered empty. | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| User entered empty. | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

[Severity](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------|----------------------|
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

Death

| Audit | User | Time (GMT) |
|------------------|---------------------------|----------------------|
| User entered '0' | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

[Life threatening](#)

| Audit | User | Time (GMT) |
|------------------|---------------------------|----------------------|
| User entered '0' | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------|---------------------------|----------------------|
| User entered '0' | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| User entered empty. | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| User entered empty. | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| User entered empty. | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| User entered empty. | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|------------------|---------------------------|----------------------|
| User entered '0' | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|------------------|---------------------------|----------------------|
| User entered '0' | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

[Other medically important event](#)

| Audit | User | Time (GMT) |
|------------------|---------------------------|----------------------|
| User entered '0' | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| User entered 'None (NONE)' | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

None

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System | 10 Nov 2020 00:16:44 |
| User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System | 10 Nov 2020 00:16:22 |
| User entered '0' | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed recorded were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' answered with 'updated dates' (Site from DM). | Antonio Gutierrez (b) (4) | 24 Nov 2020 22:32:47 |
| User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed recorded were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 23:17:50 |
| User entered '1' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:44 |
| User entered '0' | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|------------------|---------------------------|----------------------|
| User entered '0' | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

[Outcome](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System). | System | 10 Nov 2020 00:16:44 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 10 Nov 2020 00:16:44 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:44 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 10 Nov 2020 00:16:22 |
| User entered empty. | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| User entered empty. | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

[Narrative](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User entered 'Vertigo was reported as symptom alongside Fibromuscular dysplasia SAE.' | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 10 Nov 2020 00:16:22 |

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 10 Nov 2020 00:16:22 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:56:29

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Query 'Per Patient Discharge Summary, Meclizine 25 mg was prescribed to subject. Please confirm/update CM list.' canceled (Site from CRA). | (b) (4), (b) (6) | 06 Nov 2020 18:19:44 |
| User opened query 'Per Patient Discharge Summary, Meclizine 25 mg was prescribed to subject. Please confirm/update CM list.' (Site from CRA). | (b) (4), (b) (6) | 21 Oct 2020 18:49:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:14:54 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 13:44:48 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:29

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 13:47:22 |
| 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 13:47:22 |
| Data point term sent to Coder | System | 21 Aug 2020 13:46:11 |
| User entered 'Calcium' | (b) (4), (b) (6) | 21 Aug 2020 13:45:54 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:29

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:45:54 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:29

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'Osteopenia' | (b) (4), (b) (6) | 21 Aug 2020 13:45:54 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:29

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered '1800' | (b) (4), (b) (6) | 21 Aug 2020 13:45:54 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:29

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 21 Aug 2020 13:45:54 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:29

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:45:54 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:29

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 21 Aug 2020 13:45:54 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:29

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:45:54 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:29

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 21 Aug 2020 13:45:54 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:29

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:45:54 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'un UNK 2000' | (b) (4), (b) (6) | 21 Aug 2020 13:45:54 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:29

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:45:54 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:29

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 13:45:54 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:29

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:45:54 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:29

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:45:54 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:29

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Aug 2020 13:45:54 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:29

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Aug 2020 13:45:54 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:29

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 13:45:54 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:29

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 13:48:28 |
| 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 13:48:28 |
| Data point term sent to Coder | System | 21 Aug 2020 13:47:12 |
| User entered 'Magnesium' | (b) (4), (b) (6) | 21 Aug 2020 13:46:33 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:29

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM). | (b) (4), (b) (6) | 14 Nov 2020 16:53:43 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:46:33 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:29

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'Nutritional supplement' | (b) (4), (b) (6) | 21 Aug 2020 13:46:33 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:29

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered '500' | (b) (4), (b) (6) | 21 Aug 2020 13:46:33 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:29

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 21 Aug 2020 13:46:33 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:29

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:46:33 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:29

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 21 Aug 2020 13:46:33 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:29

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:46:33 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:29

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 21 Aug 2020 13:46:33 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:29

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:46:33 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'un UNK 2015' | (b) (4), (b) (6) | 21 Aug 2020 13:46:33 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:29

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:46:33 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:29

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 13:46:33 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:29

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:46:33 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:29

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:46:33 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:29

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Aug 2020 13:46:33 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:29

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Aug 2020 13:46:33 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:29

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 13:46:33 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:29

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 13:49:18 |
| 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 13:49:18 |
| Data point term sent to Coder | System | 21 Aug 2020 13:48:14 |
| User entered 'Potassium' | (b) (4), (b) (6) | 21 Aug 2020 13:47:25 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:29

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM). | (b) (4), (b) (6) | 14 Nov 2020 16:53:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:47:25 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:29

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'Nutritional supplement' | (b) (4), (b) (6) | 21 Aug 2020 13:47:25 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:29

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered '198' | (b) (4), (b) (6) | 21 Aug 2020 13:47:25 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:29

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 21 Aug 2020 13:47:25 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:29

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:47:25 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:29

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 21 Aug 2020 13:47:25 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:29

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:47:25 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:29

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 21 Aug 2020 13:47:25 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:29

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:47:25 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:29

Start date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'un UNK 2015' | (b) (4), (b) (6) | 21 Aug 2020 13:47:25 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:29

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:47:25 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:29

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 13:47:25 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:29

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:47:25 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:29

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:47:25 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:29

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Aug 2020 13:47:25 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:29

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Aug 2020 13:47:25 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:29

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 13:47:25 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:29

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| 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. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 13:51:21 |
| 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 13:51:21 |
| Data point term sent to Coder | System | 21 Aug 2020 13:50:27 |
| User entered 'Coenzyme Q10' | (b) (4), (b) (6) | 21 Aug 2020 13:49:31 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:29

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM). | (b) (4), (b) (6) | 14 Nov 2020 16:54:01 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:49:31 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:29

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'Nutritional supplement' | (b) (4), (b) (6) | 21 Aug 2020 13:49:31 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:29

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered '100' | (b) (4), (b) (6) | 21 Aug 2020 13:49:31 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:29

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 21 Aug 2020 13:49:31 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:29

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:49:31 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:29

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 21 Aug 2020 13:49:31 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:29

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:49:31 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:29

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 21 Aug 2020 13:49:31 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:29

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:49:31 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'un UNK 2017' | (b) (4), (b) (6) | 21 Aug 2020 13:49:31 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:29

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:49:31 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:29

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 13:49:31 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:29

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:49:31 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:29

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:49:31 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:29

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Aug 2020 13:49:31 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:29

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Aug 2020 13:49:31 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:29

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 13:49:31 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:29

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 13:51:21 |
| 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 13:51:21 |
| Data point term sent to Coder | System | 21 Aug 2020 13:50:28 |
| User entered 'Turmeric' | (b) (4), (b) (6) | 21 Aug 2020 13:50:24 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:29

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM). | (b) (4), (b) (6) | 14 Nov 2020 16:54:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:50:24 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:29

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'Nutritional supplement' | (b) (4), (b) (6) | 21 Aug 2020 13:50:24 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:29

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered '500' | (b) (4), (b) (6) | 21 Aug 2020 13:50:24 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:29

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 21 Aug 2020 13:50:24 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:29

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:50:24 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:29

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 21 Aug 2020 13:50:24 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:29

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:50:24 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:29

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 21 Aug 2020 13:50:24 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:29

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:50:24 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:29

Start date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'un UNK 2015' | (b) (4), (b) (6) | 21 Aug 2020 13:50:24 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:29

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:50:24 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:29

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 13:50:24 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:29

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:50:24 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:29

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:50:24 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:29

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Aug 2020 13:50:24 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:29

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Aug 2020 13:50:24 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:29

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 13:50:24 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:29

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 13:53:29 |
| 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 13:53:29 |
| Data point term sent to Coder | System | 21 Aug 2020 13:52:34 |
| User entered 'Sumatriptan' | (b) (4), (b) (6) | 21 Aug 2020 13:52:15 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:29

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:52:15 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:29

[Indication](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| 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) | 06 Oct 2020 14:21:08 |
| 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 'Migraine headaches was added to medical history on August 21, 2020.' (Site from DM). | Kevin Martinez (b) (4) | 21 Sep 2020 22:22:44 |
| 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 11:28:12 |
| User entered 'Migraine headaches' | (b) (4), (b) (6) | 21 Aug 2020 13:52:15 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:29

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered '100' | (b) (4), (b) (6) | 21 Aug 2020 13:52:15 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:29

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 21 Aug 2020 13:52:15 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:29

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:52:15 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:29

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'as needed (PRN)' | (b) (4), (b) (6) | 21 Aug 2020 13:52:15 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:29

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:52:15 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:29

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 21 Aug 2020 13:52:15 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:29

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:52:15 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'un UNK 1985' | (b) (4), (b) (6) | 21 Aug 2020 13:52:15 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:29

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:52:15 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:29

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 13:52:15 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:29

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:52:15 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:29

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:52:15 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:29

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 13:52:15 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:29

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 13:52:15 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:29

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 13:52:15 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:29

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 13:54:15 |
| 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 13:54:15 |
| Data point term sent to Coder | System | 21 Aug 2020 13:53:36 |
| User entered 'Fish oil' | (b) (4), (b) (6) | 21 Aug 2020 13:52:47 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:29

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:52:47 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:29

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'Hyperlipidemia' | (b) (4), (b) (6) | 21 Aug 2020 13:52:47 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:29

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered '100' | (b) (4), (b) (6) | 21 Aug 2020 13:52:47 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:29

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 21 Aug 2020 13:52:47 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:29

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:52:47 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:29

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 21 Aug 2020 13:52:47 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:29

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:52:47 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:29

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 21 Aug 2020 13:52:47 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:29

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:52:47 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:29

Start date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'un UNK 2015' | (b) (4), (b) (6) | 21 Aug 2020 13:52:47 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:29

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 13:52:47 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:29

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 13:52:47 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:29

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 13:52:47 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:29

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 13:52:47 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:29

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Aug 2020 13:52:47 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:29

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Aug 2020 13:52:47 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:29

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 13:52:47 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:29

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS, PRODUCT: ERENUMAB, PRODUCTSYNONYM: AIMOVIG [ERENUMAB] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 22 Sep 2020 04:56:52 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 22 Sep 2020 04:56:52 |
| Data point term sent to Coder | System | 21 Sep 2020 22:37:29 |
| User entered 'Aimovig' | Kevin Martinez (b) (4) (b) (4) | 21 Sep 2020 22:37:06 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:29

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'No (N)' | Kevin Martinez (b) (4) | 21 Sep 2020 22:37:06 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:29

[Indication](#)

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event. Else, provide clarification if this will not be recorded on AE ECRF.' answered with 'DOES NOT MEET CRITERIA FOR AE' (Site from DM). | Victoria Hernandez (b) (4) | 05 Nov 2020 19:56:26 |
| User opened query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event. Else, provide clarification if this will not be recorded on AE ECRF.' (Site from DM). DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 12:22:04 |
| User entered 'Migraine Headaches' | Kevin Martinez (b) (4) | 21 Sep 2020 22:37:06 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:29

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered '70' | Kevin Martinez (b) (4) | 21 Sep 2020 22:37:06 |
| | (b) (4) | |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:29

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'mg (mg)' | Kevin Martinez (b) (4) | 21 Sep 2020 22:37:06 |
| | (b) (4) | |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:29

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | Kevin Martinez (b) (4) | 21 Sep 2020 22:37:06 |
| | (b) (4) | |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:29

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'once (ONCE)' | Kevin Martinez (b) (4) | 21 Sep 2020 22:37:06 |
| | (b) (4) | |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:29

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | Kevin Martinez (b) (4) | 21 Sep 2020 22:37:06 |
| | (b) (4) | |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:29

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | Kevin Martinez (b) (4) (b) (4) | 21 Sep 2020 22:37:06 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:29

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered empty. | Kevin Martinez (b) (4) | 21 Sep 2020 22:37:06 |
| | (b) (4) | |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:29

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered '21 Aug 2020' | Kevin Martinez (b) (4) | 21 Sep 2020 22:37:06 |
| | (b) (4) | |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:29

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered '0' | Kevin Martinez (b) (4) | 21 Sep 2020 22:37:06 |
| | (b) (4) | |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:29

[Ongoing?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'No (N)' | Kevin Martinez (b) (4) | 21 Sep 2020 22:37:06 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:29

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered '21 Aug 2020' | Kevin Martinez (b) (4) | 21 Sep 2020 22:37:06 |
| | (b) (4) | |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:29

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:15:39 |
| User entered 'Yes (Y)' | Kevin Martinez (b) (4) | 21 Sep 2020 22:37:06 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:29

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Sep 2020 22:37:06 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:29

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Sep 2020 22:37:06 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:29

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Sep 2020 22:37:06 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:29

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: MECLOZINE, PRODUCTSYNONYM: MECLIZINE [MECLOZINE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 10 Nov 2020 00:18:38 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 10 Nov 2020 00:18:38 |
| Data point term sent to Coder | System | 10 Nov 2020 00:18:15 |
| Coding entries removed. | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:17:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:21:55 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: MECLOZINE, PRODUCTSYNONYM: MECLIZINE [MECLOZINE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 06 Nov 2020 06:09:29 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 06 Nov 2020 06:09:29 |
| Data point term sent to Coder | System | 05 Nov 2020 23:21:22 |
| User entered 'Meclizine' | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:20:53 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:29

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:21:55 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:20:53 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:29

[Indication](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| Query 'Per CDM: Please review and confirm if this pertains to 'FIBROMUSCULAR DYSPLASIA (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' answered with 'updated' (Site from DM). | Antonio Gutierrez (b) (4) | 24 Nov 2020 22:30:18 |
| User opened query 'Per CDM: Please review and confirm if this pertains to 'FIBROMUSCULAR DYSPLASIA (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' (Site from DM). | (b) (4), (b) (6) | 14 Nov 2020 17:00:24 |
| DataPoint Un-verified. | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:17:40 |
| User entered 'Vertigo' reason for change: New Information | Antonio Gutierrez (b) (4) | 10 Nov 2020 00:17:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:21:55 |
| User entered 'Dizziness due to fibromuscular dysplasia' | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:20:53 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:29

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:21:55 |
| User entered '25' | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:20:53 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:29

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:21:55 |
| User entered 'mg (mg)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:20:53 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:29

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:21:55 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:20:53 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:29

[Frequency](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:21:55 |
| User entered 'three times daily (TID)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:20:53 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:29

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:21:55 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:20:53 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:29

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:21:55 |
| User entered 'Oral (ORAL)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:20:53 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:29

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:21:55 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:20:53 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:29

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:21:55 |
| User entered '05 Sep 2020' | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:20:53 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:29

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:21:55 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:20:53 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:29

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:21:55 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:20:53 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:29

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:21:55 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:20:53 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:29

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:21:55 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:20:53 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:29

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '3' | System | 05 Nov 2020 23:20:53 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:29

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Nov 2020 23:20:53 |

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:29

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 05 Nov 2020 23:20:53 |

US3292236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:56:29

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:18:42 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:51:50 |

US3292236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:56:29

[Procedure/Surgery date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:19:37 |
| User entered '4 Sep 2020' | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:53:51 |

US3292236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:56:29

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|--------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:19:37 |
| User entered 'Brain MRI' | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:53:51 |

US3292236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:56:29

[Indication](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Un-verified. | Antonio Gutierrez (b) (4) | 24 Nov 2020 22:23:14 |
| User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Per Query Resolution | Antonio Gutierrez (b) (4) | 24 Nov 2020 22:23:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:19:37 |
| User entered 'Adverse Event (AE)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:53:51 |

US3292236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:56:29

[If indication is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:19:37 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:53:51 |

US3292236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:56:29

[Procedure/Surgery date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:19:37 |
| User entered '4 Sep 2020' | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:54:45 |

US3292236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:56:29

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|--------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:19:37 |
| User entered 'Brain MRA' | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:54:45 |

US3292236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:56:29

[Indication](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Un-verified. | Antonio Gutierrez (b) (4) | 24 Nov 2020 22:23:33 |
| User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Per Query Resolution | Antonio Gutierrez (b) (4) | 24 Nov 2020 22:23:33 |
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:19:37 |
| User entered 'Adverse Event (AE)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:54:45 |

US3292236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:56:29

If indication is Other, specify

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 16:19:37 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 23:54:45 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:46 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:19 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'USA-US072-2020-MRNA-1273-P301000001' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

Serious

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:48 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'Yes (Y)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Death](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:50 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:21 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Life threatening](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:52 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:53 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'Yes (Y)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Other medically important event](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered 'Douglas' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered 'Denham' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

Site Address: Street

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Nov 2020 15:03:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:15 |
| Un-reviewed for Safety. | System | 14 Oct 2020 13:36:22 |
| DataPoint Un-verified. | System | 14 Oct 2020 13:36:22 |
| User entered '7940 Floyd Curl Drive' | System | 14 Oct 2020 13:36:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 13:36:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Un-reviewed for Safety. | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| User entered '5430 Fredericksburg Rd, Ste. 200' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered '7940 Floyd Curl Drive' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered 'San Antonio' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

Site Address: State

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Nov 2020 15:03:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:15 |
| Un-reviewed for Safety. | System | 14 Oct 2020 13:36:22 |
| DataPoint Un-verified. | System | 14 Oct 2020 13:36:22 |
| User entered empty. | System | 14 Oct 2020 13:36:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 13:36:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Un-reviewed for Safety. | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| User entered 'TEXAS' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 16:48:54 |
| Un-reviewed for Safety. | System | 22 Sep 2020 14:49:37 |
| User entered empty. | System | 22 Sep 2020 14:49:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| User entered 'Texas' | Kevin Martinez (b) (4) | 21 Sep 2020 22:30:54 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered '78229' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Investigator Country](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: Data point set to conformant. | System | 19 Sep 2020 01:42:07 |
| User entered 'US' (non-conformant). | System | 10 Sep 2020 17:31:34 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '6' | System | 06 Nov 2020 14:31:10 |
| User entered '5' | System | 05 Nov 2020 15:03:21 |
| User entered '4' | System | 14 Oct 2020 13:36:22 |
| User entered '3' | System | 25 Sep 2020 16:49:05 |
| User entered '2' | System | 22 Sep 2020 14:49:37 |
| User entered '1' | System | 10 Sep 2020 17:31:34 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:46 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:19 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'USA-US072-2020-MRNA-1273-P301000001' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

Serious

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:48 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'Yes (Y)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Death](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:50 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:21 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Life threatening](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:52 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:53 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'Yes (Y)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Other medically important event](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered 'Douglas' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered 'Denham' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

Site Address: Street

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Nov 2020 15:03:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:15 |
| Un-reviewed for Safety. | System | 14 Oct 2020 13:36:22 |
| DataPoint Un-verified. | System | 14 Oct 2020 13:36:22 |
| User entered '7940 Floyd Curl Drive' | System | 14 Oct 2020 13:36:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 13:36:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Un-reviewed for Safety. | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| User entered '5430 Fredericksburg Rd, Ste. 200' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered '7940 Floyd Curl Drive' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered 'San Antonio' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

Site Address: State

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Nov 2020 15:03:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:15 |
| Un-reviewed for Safety. | System | 14 Oct 2020 13:36:22 |
| DataPoint Un-verified. | System | 14 Oct 2020 13:36:22 |
| User entered empty. | System | 14 Oct 2020 13:36:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 13:36:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Un-reviewed for Safety. | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| User entered 'TEXAS' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 16:48:54 |
| Un-reviewed for Safety. | System | 22 Sep 2020 14:49:37 |
| User entered empty. | System | 22 Sep 2020 14:49:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| User entered 'Texas' | Kevin Martinez (b) (4) | 21 Sep 2020 22:30:54 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered '78229' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Investigator Country](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: Data point set to conformant. | System | 19 Sep 2020 01:42:07 |
| User entered 'US' (non-conformant). | System | 10 Sep 2020 17:31:34 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '6' | System | 06 Nov 2020 14:31:10 |
| User entered '5' | System | 05 Nov 2020 15:03:21 |
| User entered '4' | System | 14 Oct 2020 13:36:22 |
| User entered '3' | System | 25 Sep 2020 16:49:05 |
| User entered '2' | System | 22 Sep 2020 14:49:37 |
| User entered '1' | System | 10 Sep 2020 17:31:34 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:56:29

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| User entered '10/Sep/2020 13:31' | System | 10 Sep 2020 17:31:34 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:56:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| User entered 'I' | (b) (4), (b) (6) | 10 Sep 2020 17:31:34 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:46 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:19 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'USA-US072-2020-MRNA-1273-P301000001' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

Serious

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:48 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'Yes (Y)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Death](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:50 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:21 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Life threatening](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:52 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:53 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'Yes (Y)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Other medically important event](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered 'Douglas' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered 'Denham' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

Site Address: Street

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Nov 2020 15:03:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:15 |
| Un-reviewed for Safety. | System | 14 Oct 2020 13:36:22 |
| DataPoint Un-verified. | System | 14 Oct 2020 13:36:22 |
| User entered '7940 Floyd Curl Drive' | System | 14 Oct 2020 13:36:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 13:36:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Un-reviewed for Safety. | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| User entered '5430 Fredericksburg Rd, Ste. 200' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered '7940 Floyd Curl Drive' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered 'San Antonio' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

Site Address: State

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Nov 2020 15:03:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:15 |
| Un-reviewed for Safety. | System | 14 Oct 2020 13:36:22 |
| DataPoint Un-verified. | System | 14 Oct 2020 13:36:22 |
| User entered empty. | System | 14 Oct 2020 13:36:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 13:36:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Un-reviewed for Safety. | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| User entered 'TEXAS' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 16:48:54 |
| Un-reviewed for Safety. | System | 22 Sep 2020 14:49:37 |
| User entered empty. | System | 22 Sep 2020 14:49:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| User entered 'Texas' | (b) (4), (b) (6) | 21 Sep 2020 22:30:54 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered '78229' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Investigator Country](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: Data point set to conformant. | System | 19 Sep 2020 01:42:07 |
| User entered 'US' (non-conformant). | System | 10 Sep 2020 17:31:34 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '6' | System | 06 Nov 2020 14:31:10 |
| User entered '5' | System | 05 Nov 2020 15:03:21 |
| User entered '4' | System | 14 Oct 2020 13:36:22 |
| User entered '3' | System | 25 Sep 2020 16:49:05 |
| User entered '2' | System | 22 Sep 2020 14:49:37 |
| User entered '1' | System | 10 Sep 2020 17:31:34 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:56:29

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| User entered '22/Sep/2020 10:49' | System | 22 Sep 2020 14:49:37 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:56:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 16:48:54 |
| User entered 'I' | (b) (4), (b) (6) | 22 Sep 2020 14:49:37 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:46 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:19 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'USA-US072-2020-MRNA-1273-P301000001' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

Serious

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:48 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'Yes (Y)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Death](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:50 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:21 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Life threatening](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:52 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:53 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'Yes (Y)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Other medically important event](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered 'Douglas' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered 'Denham' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

Site Address: Street

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Nov 2020 15:03:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:15 |
| Un-reviewed for Safety. | System | 14 Oct 2020 13:36:22 |
| DataPoint Un-verified. | System | 14 Oct 2020 13:36:22 |
| User entered '7940 Floyd Curl Drive' | System | 14 Oct 2020 13:36:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 13:36:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Un-reviewed for Safety. | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| User entered '5430 Fredericksburg Rd, Ste. 200' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered '7940 Floyd Curl Drive' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered 'San Antonio' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

Site Address: State

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Nov 2020 15:03:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:15 |
| Un-reviewed for Safety. | System | 14 Oct 2020 13:36:22 |
| DataPoint Un-verified. | System | 14 Oct 2020 13:36:22 |
| User entered empty. | System | 14 Oct 2020 13:36:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 13:36:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Un-reviewed for Safety. | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| User entered 'TEXAS' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 16:48:54 |
| Un-reviewed for Safety. | System | 22 Sep 2020 14:49:37 |
| User entered empty. | System | 22 Sep 2020 14:49:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| User entered 'Texas' | Kevin Martinez (b) (4) | 21 Sep 2020 22:30:54 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered '78229' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Investigator Country](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: Data point set to conformant. | System | 19 Sep 2020 01:42:07 |
| User entered 'US' (non-conformant). | System | 10 Sep 2020 17:31:34 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '6' | System | 06 Nov 2020 14:31:10 |
| User entered '5' | System | 05 Nov 2020 15:03:21 |
| User entered '4' | System | 14 Oct 2020 13:36:22 |
| User entered '3' | System | 25 Sep 2020 16:49:05 |
| User entered '2' | System | 22 Sep 2020 14:49:37 |
| User entered '1' | System | 10 Sep 2020 17:31:34 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:56:29

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| User entered '25/Sep/2020 16:49' | System | 25 Sep 2020 16:49:05 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:56:29

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) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 13:36:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| User entered 'I' | (b) (4), (b) (6) | 25 Sep 2020 16:49:05 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:46 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:19 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'USA-US072-2020-MRNA-1273-P301000001' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

Serious

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:48 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'Yes (Y)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Death](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:50 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:21 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Life threatening](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:52 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:53 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'Yes (Y)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Other medically important event](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered 'Douglas' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered 'Denham' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

Site Address: Street

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Nov 2020 15:03:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:15 |
| Un-reviewed for Safety. | System | 14 Oct 2020 13:36:22 |
| DataPoint Un-verified. | System | 14 Oct 2020 13:36:22 |
| User entered '7940 Floyd Curl Drive' | System | 14 Oct 2020 13:36:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 13:36:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Un-reviewed for Safety. | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| User entered '5430 Fredericksburg Rd, Ste. 200' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered '7940 Floyd Curl Drive' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered 'San Antonio' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

Site Address: State

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Nov 2020 15:03:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:15 |
| Un-reviewed for Safety. | System | 14 Oct 2020 13:36:22 |
| DataPoint Un-verified. | System | 14 Oct 2020 13:36:22 |
| User entered empty. | System | 14 Oct 2020 13:36:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 13:36:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Un-reviewed for Safety. | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| User entered 'TEXAS' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 16:48:54 |
| Un-reviewed for Safety. | System | 22 Sep 2020 14:49:37 |
| User entered empty. | System | 22 Sep 2020 14:49:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| User entered 'Texas' | Kevin Martinez (b) (4) | 21 Sep 2020 22:30:54 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered '78229' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Investigator Country](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: Data point set to conformant. | System | 19 Sep 2020 01:42:07 |
| User entered 'US' (non-conformant). | System | 10 Sep 2020 17:31:34 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '6' | System | 06 Nov 2020 14:31:10 |
| User entered '5' | System | 05 Nov 2020 15:03:21 |
| User entered '4' | System | 14 Oct 2020 13:36:22 |
| User entered '3' | System | 25 Sep 2020 16:49:05 |
| User entered '2' | System | 22 Sep 2020 14:49:37 |
| User entered '1' | System | 10 Sep 2020 17:31:34 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:56:29

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:15 |
| User entered '14/Oct/2020 13:36' | System | 14 Oct 2020 13:36:22 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:56:29

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) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Nov 2020 15:03:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:15 |
| User entered 'I' | (b) (4), (b) (6) | 14 Oct 2020 13:36:22 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:46 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:19 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'USA-US072-2020-MRNA-1273-P301000001' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

Serious

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:48 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'Yes (Y)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Death](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:50 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:21 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Life threatening](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:52 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:53 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'Yes (Y)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Other medically important event](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered 'Douglas' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered 'Denham' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

Site Address: Street

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Nov 2020 15:03:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:15 |
| Un-reviewed for Safety. | System | 14 Oct 2020 13:36:22 |
| DataPoint Un-verified. | System | 14 Oct 2020 13:36:22 |
| User entered '7940 Floyd Curl Drive' | System | 14 Oct 2020 13:36:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 13:36:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Un-reviewed for Safety. | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| User entered '5430 Fredericksburg Rd, Ste. 200' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered '7940 Floyd Curl Drive' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered 'San Antonio' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

Site Address: State

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Nov 2020 15:03:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:15 |
| Un-reviewed for Safety. | System | 14 Oct 2020 13:36:22 |
| DataPoint Un-verified. | System | 14 Oct 2020 13:36:22 |
| User entered empty. | System | 14 Oct 2020 13:36:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 13:36:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Un-reviewed for Safety. | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| User entered 'TEXAS' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 16:48:54 |
| Un-reviewed for Safety. | System | 22 Sep 2020 14:49:37 |
| User entered empty. | System | 22 Sep 2020 14:49:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| User entered 'Texas' | Kevin Martinez (b) (4) | 21 Sep 2020 22:30:54 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered '78229' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Investigator Country](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: Data point set to conformant. | System | 19 Sep 2020 01:42:07 |
| User entered 'US' (non-conformant). | System | 10 Sep 2020 17:31:34 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '6' | System | 06 Nov 2020 14:31:10 |
| User entered '5' | System | 05 Nov 2020 15:03:21 |
| User entered '4' | System | 14 Oct 2020 13:36:22 |
| User entered '3' | System | 25 Sep 2020 16:49:05 |
| User entered '2' | System | 22 Sep 2020 14:49:37 |
| User entered '1' | System | 10 Sep 2020 17:31:34 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 10:56:29

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:15:44 |
| User entered '05/Nov/2020 15:03' | System | 05 Nov 2020 15:03:21 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 10:56:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:15:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 06 Nov 2020 14:30:53 |
| User entered 'I' | (b) (4), (b) (6) | 05 Nov 2020 15:03:21 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:46 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:19 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'USA-US072-2020-MRNA-1273-P301000001' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

Serious

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:48 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'Yes (Y)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Death](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:50 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:21 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Life threatening](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:52 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:06:53 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'Yes (Y)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Other medically important event](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 17:31:25 |
| User entered 'No (N)' | System | 10 Sep 2020 17:22:57 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered 'Douglas' | System | 14 Sep 2020 22:04:16 |

US3292236

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Form: Safety Report Form

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[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered 'Denham' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

Site Address: Street

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Nov 2020 15:03:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:15 |
| Un-reviewed for Safety. | System | 14 Oct 2020 13:36:22 |
| DataPoint Un-verified. | System | 14 Oct 2020 13:36:22 |
| User entered '7940 Floyd Curl Drive' | System | 14 Oct 2020 13:36:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 13:36:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Un-reviewed for Safety. | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| User entered '5430 Fredericksburg Rd, Ste. 200' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered '7940 Floyd Curl Drive' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered 'San Antonio' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

Site Address: State

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Nov 2020 15:03:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 19:05:15 |
| Un-reviewed for Safety. | System | 14 Oct 2020 13:36:22 |
| DataPoint Un-verified. | System | 14 Oct 2020 13:36:22 |
| User entered empty. | System | 14 Oct 2020 13:36:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 13:36:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Un-reviewed for Safety. | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| User entered 'TEXAS' reason for change: Data Entry Error | Antonio Gutierrez (b) (4) | 26 Sep 2020 17:38:03 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 16:48:54 |
| Un-reviewed for Safety. | System | 22 Sep 2020 14:49:37 |
| User entered empty. | System | 22 Sep 2020 14:49:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| User entered 'Texas' | Kevin Martinez (b) (4) | 21 Sep 2020 22:30:54 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: User entered '78229' | System | 14 Sep 2020 22:04:16 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[Investigator Country](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Oct 2020 19:13:09 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Sep 2020 14:49:27 |
| Amendment Manager: Data point set to conformant. | System | 19 Sep 2020 01:42:07 |
| User entered 'US' (non-conformant). | System | 10 Sep 2020 17:31:34 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '6' | System | 06 Nov 2020 14:31:10 |
| User entered '5' | System | 05 Nov 2020 15:03:21 |
| User entered '4' | System | 14 Oct 2020 13:36:22 |
| User entered '3' | System | 25 Sep 2020 16:49:05 |
| User entered '2' | System | 22 Sep 2020 14:49:37 |
| User entered '1' | System | 10 Sep 2020 17:31:34 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 10:56:29

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:15:34 |
| User entered '06/Nov/2020 14:31' | System | 06 Nov 2020 14:31:10 |

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 10:56:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:15:36 |
| User entered 'I' | (b) (4), (b) (6) | 06 Nov 2020 14:31:10 |