

US3292320 (Prod: Clinical Trials of Texas, Inc)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:52:25

All time stamps listed in this document are displayed in GMT

US3292320

Form: Participant Creation

Generated On: 26 Nov 2020 10:52:25

[Participant ID](#)

US3292320

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

US3292320

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

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

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1966 |
| Age | 54 |
| Age Units | YEARS |
| Age (Derived) | 54 |
| Sex | Female <input type="radio"/> Male <input checked="" type="radio"/> |
| Ethnicity | Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/> |
| Race (Check All That Apply) | |
| White | True |
| Black | False |
| Asian | False |
| American Indian or Alaska Native | False |
| Native Hawaiian or other Pacific Islander | False |
| Other | False |
| If race is Other, specify _____ | |
| Unknown | False |
| Not reported | False |

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 25 AUG 2020 |
| Month and Year of Informed Consent (derived) | AUG 2020 |
| Year of Informed Consent (derived) | 2020 |
| Protocol Version | Amendment 1 <input type="radio"/> |
| | Amendment 2 <input type="radio"/> |
| | Amendment 3 <input checked="" type="radio"/> |
| | Amendment 4 <input type="radio"/> |
| | Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| If No, indicate reason for screen fail | Withdrew Consent <input type="radio"/> |
| | Inclusion/Exclusion <input type="radio"/> |
| | Cohort Full <input type="radio"/> |
| | Other <input type="radio"/> |
| If reason for screen fail is Other, specify | |
| Was this participant screened previously? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| If Yes, previous participant number | |
| Enrollment Trigger | 1 |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:52:25

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:52:25

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| Condition | SINUS SURGERY |
| Start date (dd MMM yyyy) | UN UNK 2017 |
| 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 2017 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2017 |
| Start Year (derived) | 2017 |
| Stop Month and Year (derived) | JAN 2017 |
| Stop Year (derived) | 2017 |

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:25

| | |
|---|---|
| Condition | LEFT TOE SURGERY |
| Start date (dd MMM yyyy) | UN UNK 2005 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="checkbox"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2005 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2005 |
| Start Year (derived) | 2005 |
| Stop Month and Year (derived) | JAN 2005 |
| Stop Year (derived) | 2005 |

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| Condition | DEVIATED SEPTUN |
| Start date (dd MMM yyyy) | UN UNK 2017 |
| 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 2017 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2017 |
| Start Year (derived) | 2017 |
| Stop Month and Year (derived) | JAN 2017 |
| Stop Year (derived) | 2017 |

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:52:25

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

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| Condition | INJURY TO LEFT BIG TOE |
| Start date (dd MMM yyyy) | UN UNK 2005 |
| 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 2005 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2005 |
| Start Year (derived) | 2005 |
| Stop Month and Year (derived) | JAN 2005 |
| Stop Year (derived) | 2005 |

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| Condition | SPINAL OSTEOARTHRITIS |
| Start date (dd MMM yyyy) | UN UNK 2008 |
| 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 2008 |
| Start Year (derived) | 2008 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:52:25

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

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| Condition | ADHESIVE ALLERGY |
| Start date (dd MMM yyyy) | UN UNK 2005 |
| 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 2005 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2005 |
| Start Year (derived) | 2005 |
| Stop Month and Year (derived) | JAN 2005 |
| Stop Year (derived) | 2005 |

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| Condition | LOW BACK PAIN |
| Start date (dd MMM yyyy) | UN UNK 1991 |
| 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 1991 |
| Start Year (derived) | 1991 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:52:25

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

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:52:25

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

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| Condition | OBSTRUCTIVE SLEEP APNEA |
| Start date (dd MMM yyyy) | UN UNK 2008 |
| 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 2008 |
| Start Year (derived) | 2008 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| Condition | R SHOULDER JOINT PAIN |
| Start date (dd MMM yyyy) | UN UNK 2004 |
| 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 2004 |
| Start Year (derived) | 2004 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:52:25

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

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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:52:25

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

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Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| Condition | CERVICAL RADICULOPATHY |
| Start date (dd MMM yyyy) | UN UNK 2008 |
| 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 2008 |
| Start Year (derived) | 2008 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 25 AUG 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 15:16 (24 HR) |
| Vital Signs Date and Time (derived) | 25 AUG 2020 15:16 |
| Height (<i>xxx.x</i>) | 175.5 cm |
| Weight (<i>xxx.x</i>) | 95.6 kg |
| BMI (<i>xxx.x</i>) | 31.03871 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 checked="" type="radio"/> |
| If Other, specify | ND - Not Done |
| 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 10:52:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:25

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 True

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 10:52:25

| | |
|--|-------|
| 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) | False |
| Other | False |
| Specify | |

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

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

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:52:25

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

What was the participant's randomization number? 108491

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 10:52:25

| | |
|--------|---------------|
| 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 10:52:25

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 25 AUG 2020 |
| Time of assessment (00:00-23:59) | 15:22 (24 HR) |
| Vital Signs Date and Time (derived) | 25 AUG 2020 15:22 |
| Temperature (xxx.x) | 036.4 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 075 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 016 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 149 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 089 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 25 AUG 2020 |
| Time of assessment (00:00-23:59) | 17:06 (24 HR) |
| Vital Signs Date and Time (derived) | 25 AUG 2020 17:06 |
| Temperature (xxx.x) | 36.6 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 67 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 128 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 80 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:25

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 10:52:25

| | |
|--|--|
| 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) | 25 AUG 2020 |
| What was the treatment time? (00:00-23:59) | 16:31 (24 HR) |
| Treatment Date and Time (derived) | 25 AUG 2020 16:31 |
| 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 10:52:25

| | |
|--|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (<i>dd MMM yyyy</i>) | 25 AUG 2020 |
| Collection time (<i>00:00-23:59</i>) | 15:29 (24 HR) |
| Collection date and time (derived) | 25 AUG 2020 15:29 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:52:25

| | | | |
|--|---------------------------|--|------------------------------------|
| Collection date (<i>dd MMM yyyy</i>) | | | 25 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 | 15:45 | 25 AUG 2020 15:45 |
| Nasopharyngeal Swab 2 | No | | |

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

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 10:52:25

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 17:09

PC Open Date & Time

25 AUG 2020 16:51

PC Close Date & Time

25 AUG 2020 19:21

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.7 °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 | 25 AUG 2020 21:31 |
| PC Open Date & Time | 25 AUG 2020 20:16 |
| PC Close Date & Time | 26 AUG 2020 11:59 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

27 AUG 2020 00:06

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 02:00

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

29 AUG 2020 00:33

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °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

29 AUG 2020 22:30

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:25

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

97.4 °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

30 AUG 2020 13:14

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:25

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

31 AUG 2020 22:41

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 17:07

PC Open Date & Time

25 AUG 2020 16:51

PC Close Date & Time

25 AUG 2020 19:21

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 21:32

PC Open Date & Time

25 AUG 2020 20:16

PC Close Date & Time

26 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:25

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

27 AUG 2020 00:06

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:25

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

28 AUG 2020 02:00

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:25

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

29 AUG 2020 00:33

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:25

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

29 AUG 2020 22:30

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 13:14

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 22:42

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 25 AUG 2020 17:10 |
| PC Open Date & Time | 25 AUG 2020 16:51 |
| PC Close Date & Time | 25 AUG 2020 19:21 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 25 AUG 2020 21:32 |
| PC Open Date & Time | 25 AUG 2020 20:16 |
| PC Close Date & Time | 26 AUG 2020 11:59 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

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 ☒

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

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

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

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 ☒

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 28 AUG 2020 02:01 |
| PC Open Date & Time | 27 AUG 2020 12:00 |
| PC Close Date & Time | 28 AUG 2020 11:59 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

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 ☒

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 29 AUG 2020 00:34 |
| PC Open Date & Time | 28 AUG 2020 12:00 |
| PC Close Date & Time | 29 AUG 2020 11:59 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

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 ☒

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 29 AUG 2020 22:31 |
| PC Open Date & Time | 29 AUG 2020 12:00 |
| PC Close Date & Time | 30 AUG 2020 11:59 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

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 ☒

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 30 AUG 2020 13:14 |
| PC Open Date & Time | 30 AUG 2020 12:00 |
| PC Close Date & Time | 31 AUG 2020 11:59 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

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 ☒

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 31 AUG 2020 22:42 |
| PC Open Date & Time | 31 AUG 2020 12:00 |
| PC Close Date & Time | 01 SEP 2020 11:59 |

US3292320

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

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

CONTACT NOT MADE DUE TO
ERROR

If Contact Not Made, please provide Comments

US3292320

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292320

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

Was Contact Attempted?

Yes ☒

No ☐

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

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292320

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292320

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

Was Contact Attempted?

Yes ☒

No ☐

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

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292320

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292320

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 22 SEP 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT2 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

| | |
|-------------------------------------|---|
| Timepoint | Pre-Dose <input checked="" type="radio"/> |
| | Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 22 SEP 2020 |
| Time of assessment (00:00-23:59) | 14:17 (24 HR) |
| Vital Signs Date and Time (derived) | 22 SEP 2020 14:17 |
| Temperature (xxx.x) | 36.7 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 79 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 12 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 134 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 84 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

| | |
|-------------------------------------|--|
| Timepoint | Pre-Dose <input type="radio"/> |
| | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 22 SEP 2020 |
| Time of assessment (00:00-23:59) | 16:00 (24 HR) |
| Vital Signs Date and Time (derived) | 22 SEP 2020 16:00 |
| Temperature (xxx.x) | 36.1 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 82 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 12 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 131 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 96 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

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

US3292320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:25

| | |
|--|--|
| 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) | 22 SEP 2020 |
| What was the treatment time? (00:00-23:59) | 15:30 (24 HR) |
| Treatment Date and Time (derived) | 22 SEP 2020 15:30 |
| 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 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:25

| | |
|--|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (<i>dd MMM yyyy</i>) | 22 SEP 2020 |
| Collection time (<i>00:00-23:59</i>) | 14:25 (24 HR) |
| Collection date and time (derived) | 22 SEP 2020 14:25 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:52:25

| Collection date (dd MMM yyyy) | | | 22 SEP 2020 |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 14:42 | 22 SEP 2020 14:42 |
| Nasopharyngeal Swab 2 | No | | |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 16:02

PC Open Date & Time

22 SEP 2020 15:50

PC Close Date & Time

22 SEP 2020 18:20

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

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 97.4 °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 | 23 SEP 2020 03:37 |
| PC Open Date & Time | 22 SEP 2020 19:15 |
| PC Close Date & Time | 23 SEP 2020 11:59 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 19:29

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 02:38

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 20:46

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

26 SEP 2020 23:10

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:25

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

28 SEP 2020 00:43

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:25

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

97.7 °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

28 SEP 2020 23:37

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 16:03

PC Open Date & Time

22 SEP 2020 15:50

PC Close Date & Time

22 SEP 2020 18:20

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

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

23 SEP 2020 03:38

PC Open Date & Time

22 SEP 2020 19:15

PC Close Date & Time

23 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:25

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

23 SEP 2020 19:29

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:25

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

25 SEP 2020 02:38

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 20:46

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:25

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

26 SEP 2020 23:11

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 00:43

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 23:37

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 22 SEP 2020 16:03 |
| PC Open Date & Time | 22 SEP 2020 15:50 |
| PC Close Date & Time | 22 SEP 2020 18:20 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 23 SEP 2020 03:38 |
| PC Open Date & Time | 22 SEP 2020 19:15 |
| PC Close Date & Time | 23 SEP 2020 11:59 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

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 ☒

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 23 SEP 2020 19:30 |
| PC Open Date & Time | 23 SEP 2020 12:00 |
| PC Close Date & Time | 24 SEP 2020 11:59 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

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 ☒

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 25 SEP 2020 02:38 |
| PC Open Date & Time | 24 SEP 2020 12:00 |
| PC Close Date & Time | 25 SEP 2020 11:59 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

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 ☒

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 25 SEP 2020 20:47 |
| PC Open Date & Time | 25 SEP 2020 12:00 |
| PC Close Date & Time | 26 SEP 2020 11:59 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

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 ☒

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 26 SEP 2020 23:11 |
| PC Open Date & Time | 26 SEP 2020 12:00 |
| PC Close Date & Time | 27 SEP 2020 11:59 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

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 ☒

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 28 SEP 2020 00:43 |
| PC Open Date & Time | 27 SEP 2020 12:00 |
| PC Close Date & Time | 28 SEP 2020 11:59 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

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 ☒

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 28 SEP 2020 23:38 |
| PC Open Date & Time | 28 SEP 2020 12:00 |
| PC Close Date & Time | 29 SEP 2020 11:59 |

US3292320

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

Was Contact Attempted?

Yes ☒

No ☐

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

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

If Contact Not Made, please provide Comments

3 ATTEMPTS MADE TO
SUBJECT, CALL WENT
STRAIGHT TO VOICEMAIL,
VOICEMAIL BOX FULL UNABLE
TO LVM.

US3292320

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292320

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

Was Contact Attempted?

Yes ☒

No ☐

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

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292320

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292320

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

Was Contact Attempted?

Yes ☒

No ☐

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

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292320

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292320

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 21 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 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

| | |
|---|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 21 OCT 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 10:50 (24 HR) |
| Vital Signs Date and Time (derived) | 21 OCT 2020 10:50 |
| Temperature (<i>xxx.x</i>) | 36.6 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | 90 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | 151 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | 89 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:25

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.

US3292320

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:25

| | |
|--|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (<i>dd MMM yyyy</i>) | 21 OCT 2020 |
| Collection time (<i>00:00-23:59</i>) | 11:07 (24 HR) |
| Collection date and time (derived) | 21 OCT 2020 11:07 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

26 OCT 2020 09:29:15

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

01 NOV 2020 04:15:25

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

09 NOV 2020 10:11:45

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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="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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

26 OCT 2020 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

02 NOV 2020 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

09 NOV 2020 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

16 NOV 2020 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 00:20:49

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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="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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 14 DEC 2020 23:59 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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="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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| TIMEPOINT | DAY 152 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 25 JAN 2021 23:59 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| TIMEPOINT | DAY 159 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| TIMEPOINT | DAY 166 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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="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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 22 FEB 2021 23:59 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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 <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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 22 MAR 2021 23:59 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 29 MAR 2021 23:59 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| TIMEPOINT | DAY 250 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| TIMEPOINT | DAY 257 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

DAY 264

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

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

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 27 MAY 2021 00:01 |
| Patient Cloud Close Date & Time | 31 MAY 2021 23:59 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 JUN 2021 00:01 |
| Patient Cloud Close Date & Time | 14 JUN 2021 23:59 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| TIMEPOINT | DAY 320 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 22 JUL 2021 00:01 |
| Patient Cloud Close Date & Time | 26 JUL 2021 23:59 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| TIMEPOINT | DAY 383 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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="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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| TIMEPOINT | DAY 411 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

DAY 432

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

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

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

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

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

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 25 NOV 2021 00:01 |
|--|-------------------|

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 29 NOV 2021 23:59 |
|---|-------------------|

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| TIMEPOINT | DAY 467 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| TIMEPOINT | DAY 481 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| TIMEPOINT | DAY 495 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 13 JAN 2022 00:01 |
| Patient Cloud Close Date & Time | 17 JAN 2022 23:59 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 MAR 2022 00:01 |
| Patient Cloud Close Date & Time | 14 MAR 2022 23:59 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐
Yes ☐

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐ Yes ☐

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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°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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐
Yes ☐

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 11 JUL 2022 23:59 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 18 JUL 2022 23:59 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 25 JUL 2022 23:59 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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="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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| 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"/> |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

DAY 726

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

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

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

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

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

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 AUG 2022 00:01 |
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| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 29 AUG 2022 23:59 |
|---|-------------------|

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 20 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 24 OCT 2022 23:59 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

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

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

US3292320

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

Was Contact Attempted?

Yes ☒

No ☐

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

17 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292320

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292320

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

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

US3292320

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:52:25

| | |
|--|---|
| Date of Contact | 17 NOV 2020 |
| Time of Contact | 16:04 |
| Date and Time of Contact (derived) | 17 NOV 2020 16:04 |
| Type of Contact | Clinic Visit - Scheduled <input type="checkbox"/> |
| | Clinical Visit - Unscheduled <input type="checkbox"/> |
| | Safety Call <input checked="" type="checkbox"/> |
| | Convalescent Tele-visit <input type="checkbox"/> |
| Has the subject reported symptoms of SARS-COV-2? | Yes <input checked="" type="checkbox"/> |
| | No <input type="checkbox"/> |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input checked="" type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |
| Day 33 | <input type="checkbox"/> |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

| | | |
|----------------------|----------------------|-------------------------------------|
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 15 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | <input type="text"/> | |
| O2 Saturation Units | <input type="text"/> | |
| Temperature | <input type="text"/> | |
| Chills | None | <input type="checkbox"/> |
| | Mild | <input checked="" type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Cough | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Shortness of Breath | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Difficulty Breathing | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Fatigue | None | <input type="checkbox"/> |
| v6.020 DTW (1102) | 346 of 2480 | |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

| | | |
|------------------------|----------|-------------------------------------|
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Muscle Aches (Myalgia) | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Body Aches | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input checked="" type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Headache | None | <input type="checkbox"/> |
| | Mild | <input checked="" type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| New Loss of Taste | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| New Loss of Smell | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Nasal Congestion | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

| | | |
|-------------------------|----------|--------------------------|
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Runny Nose (Rhinorrhea) | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Nausea | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Vomiting | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Diarrhea | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Sore Throat | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input checked="" type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |
| Day 33 | <input type="checkbox"/> |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

| | | |
|----------------------|----------------------|-------------------------------------|
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 16 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | <input type="text"/> | |
| O2 Saturation Units | <input type="text"/> | |
| Temperature | <input type="text"/> | |
| Chills | None | <input type="checkbox"/> |
| | Mild | <input checked="" type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Cough | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Shortness of Breath | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Difficulty Breathing | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Fatigue | None | <input type="checkbox"/> |
| v6.020 DTW (1102) | 350 of 2480 | |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

| | | |
|------------------------|----------|-------------------------------------|
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Muscle Aches (Myalgia) | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Body Aches | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input checked="" type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Headache | None | <input type="checkbox"/> |
| | Mild | <input checked="" type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| New Loss of Taste | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| New Loss of Smell | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Nasal Congestion | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

| | | |
|-------------------------|----------|--------------------------|
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Runny Nose (Rhinorrhea) | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Nausea | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Vomiting | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Diarrhea | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Sore Throat | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input checked="" type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |
| Day 33 | <input type="checkbox"/> |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

| | | |
|----------------------|----------------------|-------------------------------------|
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 17 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | <input type="text"/> | |
| O2 Saturation Units | <input type="text"/> | |
| Temperature | <input type="text"/> | |
| Chills | None | <input type="checkbox"/> |
| | Mild | <input checked="" type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Cough | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Shortness of Breath | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Difficulty Breathing | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Fatigue | None | <input type="checkbox"/> |
| v6.020 DTW (1102) | 354 of 2480 | |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

| | | |
|------------------------|----------|-------------------------------------|
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Muscle Aches (Myalgia) | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Body Aches | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input checked="" type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Headache | None | <input type="checkbox"/> |
| | Mild | <input checked="" type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| New Loss of Taste | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| New Loss of Smell | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Nasal Congestion | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

| | | |
|-------------------------|----------|--------------------------|
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Runny Nose (Rhinorrhea) | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Nausea | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Vomiting | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Diarrhea | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Sore Throat | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input checked="" type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |
| Day 33 | <input type="checkbox"/> |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

| | | |
|----------------------|-------------|-------------------------------------|
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 18 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 36.8 C | |
| Chills | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input checked="" type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Cough | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input checked="" type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Shortness of Breath | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Difficulty Breathing | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Fatigue | None | <input type="checkbox"/> |
| v6.020 DTW (1102) | 358 of 2480 | |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

| | | |
|------------------------|----------|----------------------------------|
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nasal Congestion | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

| | | |
|-------------------------|----------|----------------------------------|
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Runny Nose (Rhinorrhea) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nausea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Vomiting | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Diarrhea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Sore Throat | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input checked="" type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |
| Day 33 | <input type="checkbox"/> |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

| | | |
|----------------------|-------------|----------------------------------|
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 19 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 37.5 C | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| v6.020 DTW (1102) | 362 of 2480 | |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

| | | |
|------------------------|----------|----------------------------------|
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nasal Congestion | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

| | | |
|-------------------------|----------|-------------------------------------|
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Runny Nose (Rhinorrhea) | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Nausea | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Vomiting | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Diarrhea | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Sore Throat | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input checked="" type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |
| Day 33 | <input type="checkbox"/> |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

| | | |
|----------------------|-------------|----------------------------------|
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 20 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 36.8 C | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| v6.020 DTW (1102) | 366 of 2480 | |

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

| | | |
|------------------------|----------|----------------------------------|
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nasal Congestion | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

| | | |
|-------------------------|----------|-------------------------------------|
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Runny Nose (Rhinorrhea) | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Nausea | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Vomiting | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Diarrhea | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Sore Throat | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input checked="" type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |
| Day 33 | <input type="checkbox"/> |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

| | | |
|----------------------|-------------|----------------------------------|
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 21 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 96 % | |
| O2 Saturation Units | % | |
| Temperature | 36.2 C | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| v6.020 DTW (1102) | 370 of 2480 | |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

| | | |
|------------------------|----------|----------------------------------|
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nasal Congestion | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

| | | |
|-------------------------|----------|-------------------------------------|
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Runny Nose (Rhinorrhea) | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Nausea | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Vomiting | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Diarrhea | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Sore Throat | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| Date of Visit | 18 NOV 2020 |
| Was the Subject Tested For SARS-CoV-2 by RT-PCR? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Did Subject Test Positive For SARS-CoV-2 by RT-PCR? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of Test | 18 NOV 2020 |
| Type of Test Performed | Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/> |
| Other, specify _____ | |
| Was this diagnostic test performed at a lab other than the Study Central Lab? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If yes, provide lab information below | |
| Lab/ Institution Test Performed | _____ |
| CLIA Certified? | Yes <input type="radio"/> No <input type="radio"/> |
| COVID-19 Positive (CSA Programming Field Only) | 1 |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:52:25

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

If Yes to either Did subject require any of the following:

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:52:25

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date _____

End Date _____

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date _____

End Date _____

Mechanical Ventilation? Yes ☐
No ☐

Start Date _____

End Date _____

ECMO? Yes ☐
No ☐

Start Date _____

End Date _____

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐
No ☐

Start Date _____

End Date _____

Evidence of Shock Requires Vasopressors Yes ☐
No ☐

Start Date _____

End Date _____

Acute Renal Dysfunction? Yes ☐
No ☐

Start Date _____

Hepatic Dysfunction? Yes ☐
No ☐

Start Date _____

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:52:25

Neurologic Dysfunction? Yes ☐
No ☐

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☐

Date of Assessment

Radiographical Evidence Yes ☐
No ☐

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:52:25

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:52:25

| Visit | Was Saliva Collected? | Date of Collection |
|--------|-----------------------|--------------------|
| Day 3 | Yes | 20 NOV 2020 |
| Day 5 | Yes | 22 NOV 2020 |
| Day 7 | | |
| Day 9 | | |
| Day 14 | | |
| Day 21 | | |
| Day 28 | | |

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

| | |
|---|---------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 18 NOV 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input checked="" type="radio"/> |
| | Clinic <input type="radio"/> |
| Folder OID | SICKD1 |

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

| | |
|---|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 18 NOV 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 15:27 (24 HR) |
| Vital Signs Date and Time (derived) | 18 NOV 2020 15:27 |
| Height (<i>xxx.x</i>) | 175.3 cm |
| Weight (<i>xxx.x</i>) | 92.5 kg |
| Temperature (<i>xxx.x</i>) | 36.8 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | 79 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 17 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | 139 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | 79 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 NOV 2020

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

US3292320

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 10:52:25

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

18 NOV 2020

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Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3292320

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

| | |
|---|-----------------------------------|
| Were vital signs assessed? | Yes <input type="checkbox"/> |
| | No <input type="checkbox"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | |
| Time of assessment (<i>00:00-23:59</i>) | |
| Vital Signs Date and Time (derived) | |
| Temperature (<i>xxx.x</i>) | |
| Route of measurement | Oral <input type="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | |
| Pulse units | |
| Respiratory Rate (<i>xxx</i>) | |
| Respiratory Rate units | |
| Systolic Blood Pressure (<i>xxx</i>) | |
| Systolic Blood Pressure units | |
| Diastolic Blood Pressure (<i>xxx</i>) | |
| Diastolic Blood Pressure units | |
| Height (derived) | |
| Weight (derived) | |

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:25

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: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 10:52:25

| | | |
|--|------------------------|--------------------------|
| Was Blood Sample Taken for Immunologic Assessment of | Yes | <input type="checkbox"/> |
| SARS_COV-2 Infection? | No | <input type="checkbox"/> |
| | NA (COVID-19 Negative) | <input type="checkbox"/> |

| | |
|--------------------|--|
| Date of Collection | |
|--------------------|--|

US3292320

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:52:25

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

| | |
|--|--|
| AEID | USA-US072-2020-MRNA-1273-P30 1000003 |
| Adverse event | LEFT HIP LABRUM TEAR |
| 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) | 27 AUG 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 30 AUG 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 4 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) | 388 of 2480 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

| | |
|--|---|
| 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 | 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 type="radio"/> Unknown <input checked="" type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | PATIENT REPORTED TO CLINIC ON 22SEP2020 FOR V2. DURING HIS VISIT, HE REPORTED TO SUB-I AND CRC THAT HE WAS ACTUALLY ADMITTED TO THE HOSPITAL DUE TO WHAT WAS LATER DIAGNOSED AS A RIGHT HIP LABRUM TEAR. WILL UPDATE THIS POST AS MORE INFORMATION IS COLLECTED. |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

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

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

| | |
|--|--|
| AEID | |
| Adverse event | LEUKOCYTOSIS |
| 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) | 30 AUG 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) | 4 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 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) | 391 of 2480 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

| | |
|--|--|
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | <div>Not Related <input checked="" type="radio"/></div> <div>Related <input type="radio"/></div> <div>Not Applicable <input type="radio"/></div> |
| Relationship to Study Procedure | <div>Not Related <input checked="" type="radio"/></div> <div>Related <input type="radio"/></div> <div>Not Applicable <input type="radio"/></div> |
| Action taken with investigational product | <div>None <input checked="" type="radio"/></div> <div>Dose Delayed <input type="radio"/></div> <div>Investigational Product Withdrawn <input type="radio"/></div> <div>Not Applicable <input type="radio"/></div> |
| Other action taken (check all that apply) | |
| None | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | <div>Fatal <input type="radio"/></div> <div>Not Recovered/Not Resolved <input type="radio"/></div> <div>Recovered/Resolved <input checked="" type="radio"/></div> <div>Recovered/Resolved with Sequelae <input type="radio"/></div> <div>Recovering/Resolving <input type="radio"/></div> <div>Unknown <input type="radio"/></div> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | DISCOVERED WHILE PATIENT WAS HOSPITALIZED DUE TO TORN LABRUM. PATIENT CONTINUED TO BE AFEBRILE. PRIMARY DIFFERENTIAL BELIEVED TO BE LEUKOCYTOSIS SECONDARY TO STEROID USE. |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

Admitted to ICU Derived (CSA Programming Field Only)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

AEID

Adverse event

URINARY RETENTION

Was this a medically-attended AE?

Yes ☒
No ☐

Was this a Solicited Adverse Reaction?

Yes ☐
No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐
No ☒

Start date (dd MMM yyyy)

30 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy)

4 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

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

Is the adverse event serious?

Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

| | |
|--|---|
| 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 | False |
| Concomitant Procedure | True |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | DISCOVERED WHILE PATIENT WAS HOSPITALIZED FOR TORN LABRUM. CATHETER WAS PLACED, NO FURTHER INTERVENTION REQUIRED. |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

| | |
|--|--|
| AEID | |
| Adverse event | FORAMINAL STENOSIS L4/L5 |
| 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) | 30 AUG 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 |

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Folder: Adverse Events

Form: Adverse Events (4)

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| | |
|--|---|
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/> |
| Other action taken (check all that apply) | |
| None | True |
| Concomitant Medication | False |
| 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 type="radio"/> Unknown <input checked="" type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | DISCOVERED WHILE PATIENT WAS HOSPITALIZED FOR TORN LABRUM. PATIENT WAS DUE TO FOLLOW UP WITH NEUROSURGERY, BUT AT LAST VISIT, PATIENT STATES HE WAS NOT MOVING FORWARD WITH ANY SURGICAL INTERVENTION. |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
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Folder: Adverse Events

Form: Adverse Events (4)

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Admitted to ICU Derived (CSA Programming Field Only)

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

AEID

Adverse event

BILATERAL HIP
OSTEOARTHRITIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

30 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

| | |
|--|---|
| 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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input checked="" type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | DISCOVERED WHILE PATIENT WAS HOSPITALIZED FOR TORN LABRUM. NO ADDITIONAL INTERVENTIONS NOTED. PT ALREADY HAD A MEDICAL HISTORY OF GENERAL OSTEOARTHRITIS. |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

Admitted to ICU Derived (CSA Programming Field Only)

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

| | |
|--|--|
| AEID | |
| Adverse event | TROCHANTERIC BURSITIS |
| 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) | 30 AUG 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 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

| | |
|--|---|
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/> |
| Other action taken (check all that apply) | |
| None | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input checked="" type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | DISCOVERED WHILE PATIENT WAS HOSPITALIZED FOR TORN LABRUM. NO FURTHER INTERVENTION NOTED. PATIENT WAS TO FOLLOW UP WITH PAIN SPECIALISTS AND NEUROSURGERY, BUT PATIENT OPTED OUT OF ANY SURGICAL INTERVENTIONS. |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
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Folder: Adverse Events

Form: Adverse Events (6)

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Admitted to ICU Derived (CSA Programming Field Only)

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

| | |
|--|--|
| AEID | |
| Adverse event | ILIOTIBIAL BAND SYNDROME |
| 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) | 30 AUG 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 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

| | |
|--|---|
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/> |
| Other action taken (check all that apply) | |
| None | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input checked="" type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | DISCOVERED WHILE PATIENT WAS HOSPITALIZED FOR TORN LABRUM. NO FURTHER INTERVENTION NOTED. PATIENT WAS TO FOLLOW UP WITH PAIN SPECIALISTS AND NEUROSURGERY, BUT PATIENT OPTED OUT OF ANY SURGICAL INTERVENTIONS. |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
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Folder: Adverse Events

Form: Adverse Events (7)

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Admitted to ICU Derived (CSA Programming Field Only)

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

| | |
|--|--|
| AEID | USA-US072-2020-MRNA-1273-P30 1000014 |
| Adverse event | POSITIVE SYMPTOMATIC COVID-19 |
| 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 checked="" type="radio"/> No <input type="radio"/> |
| Start date (dd MMM yyyy) | 15 NOV 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

| | |
|--|--|
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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 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 | SYMPTOMS STARTED 15-NOV, ILLNESS VISIT OCCURED ON 18-NOV. POSITIVE ALERT ON 23-NOV. PATIENT WITH RECENT TRAVEL OUT OF STATE |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:52:25

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:25

| | |
|--------------------------------|--|
| Name of Medication | ASPIRIN |
| Prophylaxis | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Indication | PREVENTATIVE HEART HEALTH |
| Dose per administration | 81 |
| 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 type="radio"/> unknown <input type="radio"/> other <input checked="" 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:25

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:25

| | |
|--------------------------------------|---|
| Name of Medication | MOTRIN (IBUPROFEN) |
| Prophylaxis | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> |
| Indication | GENERALIZED OSTEOARTHRITIS PAIN |
| Dose per administration | 200 |
| Dose unit | mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/> |
| If dose unit is Other, specify _____ | |
| Frequency | once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/> |
| If frequency is Other, specify _____ | |
| Route of administration | Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:25

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | UN UNK 1990 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | | _____ |
| Interval Dosage Unit Number (derived) | | _____ |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:25

| | |
|--------------------------------|--|
| Name of Medication | AMLODIPINE |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | HYPERTENSION |
| Dose per administration | 10 |
| 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 checked="" 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:25

| | | |
|---|--------------------------|----------------------------------|
| | 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 2018 |
| 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) | 2 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:25

| | |
|--------------------------------------|--|
| Name of Medication | GABAPENTIN |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | SPINAL OSTEOARTHRITIS |
| 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 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:25

| | | |
|---|--------------------------|----------------------------------|
| | 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 2008 |
| 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) | <input type="text"/> | |
| Interval Dosage Unit Number (derived) | <input type="text"/> | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:52:25

| | |
|--------------------------------|--|
| Name of Medication | TESTOSTERONE TREATMENT |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | LOW TESTOSTERONE |
| Dose per administration | |
| Dose unit | mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input 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 checked="" 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 type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/> |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:52:25

| | | |
|---|--------------------------|----------------------------------|
| | 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 2008 |
| 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 checked="" type="radio"/> |
| | 804 | <input type="radio"/> |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:52:25

| | |
|--------------------------------|--|
| Name of Medication | ATORVASTATIN |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | HYPERCHOLESTEROLEMIA |
| Dose per administration | 30 |
| 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"/> |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:52:25

| | | |
|---|--------------------------|----------------------------------|
| | 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 2018 |
| 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"/> |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:52:25

| | |
|--------------------------------|--|
| Name of Medication | METHYLPREDNISOLONE |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | TEAR IN LEFT HIP LABRUM |
| Dose per administration | 4 |
| 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"/> |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:52:25

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

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:52:25

| | |
|--------------------------------|--|
| Name of Medication | FLEXERIL |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | TEAR IN LEFT HIP LABRIUM |
| Dose per administration | 10 |
| 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"/> |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:52:25

| | | |
|---|--------------------------|----------------------------------|
| | 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) | | <input type="text"/> |
| Interval Dosage Unit Number (derived) | | <input type="text"/> |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:52:25

| | |
|--------------------------------|---|
| Name of Medication | CYCLOBENZAPRINE |
| Prophylaxis | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> |
| Indication | TEAR IN LEFT HIP LABRUM |
| Dose per administration | 10 |
| Dose unit | mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/> |
| If dose unit is Other, specify | |
| Frequency | once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/> |
| If frequency is Other, specify | |
| Route of administration | Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/> |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:52:25

| | | |
|---|--------------------------|----------------------------------|
| | 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) | | <input type="text"/> |
| Interval Dosage Unit Number (derived) | | <input type="text"/> |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

US3292320

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:52:25

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 10:52:25

| Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>) | Procedure/Surgery | Indication | If indication is Other, specify |
|---|------------------------|---------------|---------------------------------|
| 2 SEP 2020 | LUMBAR/HIP MRI W & W/O | Adverse Event | |

US3292320

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:52:25

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:52:25

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 ☐

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

| | |
|--|---|
| SAEID | USA-US072-2020-MRNA-1273-P301000003 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | 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) | 4 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| SAEID | USA-US072-2020-MRNA-1273-P301000003 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | 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) | 4 |
| Date of submission (Pre-filled from custom function) | 23/SEP/2020 10:39 |
| 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 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:52:25

| | |
|---|---|
| SAEID | USA-US072-2020-MRNA-1273-P301000003 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | 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) | 4 |
| Date of submission (Pre-filled from custom function) | 14/OCT/2020 11:16 |
| 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 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| SAEID | USA-US072-2020-MRNA-1273-P301000003 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | 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) | 4 |
| Date of submission (Pre-filled from custom function) | 05/NOV/2020 09:02 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:52:25

| | |
|---|---|
| SAEID | USA-US072-2020-MRNA-1273-P301000003 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | 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) | 4 |
| Date of submission (Pre-filled from custom function) | 06/NOV/2020 13:14 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

| | |
|--|--|
| SAEID | USA-US072-2020-MRNA-1273-P301000014 |
| Serious | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input 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) | 1 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:52:25

| | |
|---|--|
| SAEID | USA-US072-2020-MRNA-1273-P301000014 |
| Serious | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input 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) | 1 |
| Date of submission (Pre-filled from custom function) | 24/NOV/2020 13:55 |
| 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

US3292320 (Prod: Clinical Trials of Texas, Inc)

US3292320

Form: Participant Creation

Generated On: 26 Nov 2020 10:52:25

[Participant ID](#)

| Audit | User | Time (GMT) |
|--------------------------|---|----------------------|
| User entered 'US3292320' | RWS_ENDPOINT ENDPOINT (b) (4) <div></div> | 25 Aug 2020 20:34:24 |

US3292320

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:47:28 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 18:49:50 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:47:28 |
| User entered '25 AUG 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 25 Aug 2020 20:34:25 |

US3292320

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:47:28 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 27 Aug 2020 18:49:50 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'SCRN' | System | 27 Aug 2020 18:49:50 |

US3292320

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:25

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:47:37 |
| User entered (b) (6) 1966' | RWS_ENDPOINT ENDPOINT (b) (4) | 25 Aug 2020 20:34:26 |

US3292320

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:25

[Age](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:47:37 |
| User entered '54' | (b) (4), (b) (6) | 27 Aug 2020 18:49:57 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:25

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| User entered 'YEARS' | System | 27 Aug 2020 18:49:57 |

US3292320

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:25

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '54' | System | 25 Aug 2020 21:39:31 |

US3292320

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:25

Sex

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1 and Visit2 Day29: Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you.' (Site from DM). | (b) (4), (b) (6) | 13 Nov 2020 12:18:13 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:47:37 |
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1 and Visit2 Day29: Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you.' answered with 'CRC updating' (Site from DM). | Dawn Killian (b) (4) | 20 Oct 2020 20:32:54 |
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1 and Visit2 Day29: Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you.' (Site from DM). | (b) (4), (b) (6) | 16 Oct 2020 13:00:28 |
| User entered 'Male (M)' | (b) (4), (b) (6) | 27 Aug 2020 18:49:57 |

US3292320

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:25

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:47:37 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4), (b) (6) | 27 Aug 2020 18:49:57 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:25

[White](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:47:37 |
| User entered 'I' | (b) (4), (b) (6) | 27 Aug 2020 18:49:57 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:25

[Black](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:47:37 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:49:57 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:25

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:47:37 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:49:57 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:25

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:47:37 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:49:57 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:25

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:47:37 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:49:57 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:25

[Other](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:47:37 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:49:57 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:25

[If race is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:47:37 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 18:49:57 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:25

[Unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:47:37 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:49:57 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:25

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:47:37 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:49:57 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:25

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:48:01 |
| User entered '25 Aug 2020' | (b) (4), (b) (6) | 25 Aug 2020 21:39:31 |

US3292320

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Aug 2020' | System | 25 Aug 2020 21:39:31 |

US3292320

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2020' | System | 25 Aug 2020 21:39:31 |

US3292320

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:25

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:48:01 |
| User entered 'Amendment 3 (3)' | (b) (4), (b) (6) | 25 Aug 2020 21:39:31 |

US3292320

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:48:01 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Aug 2020 21:39:31 |

US3292320

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:48:01 |
| User entered empty. | (b) (4), (b) (6) | 25 Aug 2020 21:39:31 |

US3292320

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:25

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:48:01 |
| User entered empty. | (b) (4), (b) (6) | 25 Aug 2020 21:39:31 |

US3292320

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:25

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:48:01 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Aug 2020 21:39:31 |

US3292320

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:25

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:48:01 |
| User entered empty. | RWS_ENDPOINT ENDPOINT (b) (4) | 25 Aug 2020 20:34:25 |

US3292320

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:25

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 25 Aug 2020 21:39:37 |

US3292320

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:52:25

Did the participant meet all eligibility criteria?

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Aug 2020 21:39:37 |
| | | |

US3292320

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:52:25

Were any significant conditions reported?

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Query 'Per hospital discharge summary, subject has adhesive tape allergy. Please confirm and add to MH (or AE log) as appropriate.' answered with 'updated' (Site from CRA). | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:33:15 |
| Query 'Per hospital discharge summary dated 04SEP2020, subject was shown to have the following ongoing conditions that were not listed on the Medical History Log: low back pain, colonic polyp, hypogonadism, OSA, shoulder joint pain, constipation, hyperlipidemia, cervical radiculopathy. Please confirm onset dates with subject, and update medical history log (or adverse events log) as necessary.' answered with 'updated' (Site from CRA). | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:33:09 |
| User opened query 'Per hospital discharge summary, subject has adhesive tape allergy. Please confirm and add to MH (or AE log) as appropriate.' (Site from CRA). | (b) (4), (b) (6) | 23 Oct 2020 21:01:48 |
| User opened query 'Per hospital discharge summary dated 04SEP2020, subject was shown to have the following ongoing conditions that were not listed on the Medical History Log: low back pain, colonic polyp, hypogonadism, OSA, shoulder joint pain, constipation, hyperlipidemia, cervical radiculopathy. Please confirm onset dates with subject, and update medical history log (or adverse events log) as necessary.' (Site from CRA). | (b) (4), (b) (6) | 23 Oct 2020 18:50:49 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 23 Oct 2020 18:49:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 18:49:54 |
| Query 'Per hospital discharge summary dated 04SEP2020, subject was shown to have the following ongoing conditions that were not listed on the Medical History Log: low back pain colonic polyp hypogonadism OSA shoulder joint pain constipation hyperlipidemia cervical radiculopathy Please confirm onset dates with subject, and update medical history log or adverse even log as necessary.' canceled (Site from CRA). | (b) (4), (b) (6) | 23 Oct 2020 18:49:47 |

US3292320

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:52:25

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| User opened query 'Per hospital discharge summary dated 04SEP2020, subject was shown to have the following ongoing conditions that were not listed on the Medical History Log: low back pain colonic polyp hypogonadism OSA shoulder joint pain constipation hyperlipidemia cervical radiculopathy Please confirm onset dates with subject, and update medical history log or adverse even log as necessary.' (Site from CRA). DataPoint Un-verified. | (b) (4), (b) (6) [REDACTED] | 23 Oct 2020 18:47:37 |
| DataPoint Verified. | (b) (4), (b) (6) [REDACTED] | 23 Oct 2020 18:45:15 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) [REDACTED] [REDACTED] | 22 Oct 2020 20:49:35 |
| | (b) (4), (b) (6) [REDACTED] [REDACTED] | 27 Aug 2020 18:50:23 |

US3292320

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:52:25

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Paranasal therapeutic procedures, PT: Sinus operation, LLT: Sinus operation - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 27 Aug 2020 19:50:30 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 27 Aug 2020 19:50:30 |
| Data point term sent to Coder | System | 27 Aug 2020 18:51:27 |
| User entered 'sinus surgery' | (b) (4), (b) (6) | 27 Aug 2020 18:50:43 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered 'un UNK 2017' | (b) (4), (b) (6) | 27 Aug 2020 18:50:43 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:52:25

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:50:43 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:52:25

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 18:50:43 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered 'un UNK 2017' | (b) (4), (b) (6) | 27 Aug 2020 18:50:43 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:52:25

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:50:43 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2017' | System | 27 Aug 2020 18:50:43 |

US3292320

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2017' | System | 27 Aug 2020 18:50:43 |

US3292320

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2017' | System | 27 Aug 2020 18:50:43 |

US3292320

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2017' | System | 27 Aug 2020 18:50:43 |

US3292320

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:25

Condition

| Audit | User | Time (GMT) |
|--|---------------------------------------|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Toe operation, LLT: Toe operation - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 22 Oct 2020 20:51:40 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 22 Oct 2020 20:51:40 |
| Data point term sent to Coder | System | 22 Oct 2020 20:50:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User closed query 'Per DM CLR: Please specify the location ((bilateral, left, right big toe, etc.) and type of TOE SURGERY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM). | (b) (4), (b) (6) | 08 Oct 2020 14:39:48 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Toe operation, LLT: Toe operation - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 24 Sep 2020 00:19:39 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 24 Sep 2020 00:19:39 |
| Data point term sent to Coder | System | 23 Sep 2020 15:54:36 |
| Query 'Per DM CLR: Please specify the location ((bilateral, left, right big toe, etc.) and type of TOE SURGERY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'UPDATED' (Site from DM). | Victoria Hernandez (b) (4) (b) (4) | 23 Sep 2020 15:53:45 |
| Coding entries removed. | Victoria Hernandez (b) (4) (b) (4) | 23 Sep 2020 15:53:41 |
| User entered 'LEFT TOE SURGERY' reason for change: Data Entry Error | Victoria Hernandez (b) (4) (b) (4) | 23 Sep 2020 15:53:41 |
| User opened query 'Per DM CLR: Please specify the location ((bilateral, left, right big toe, etc.) and type of TOE SURGERY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM). | (b) (4), (b) (6) | 09 Sep 2020 19:04:35 |

US3292320

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:25

Condition

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLG: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Toe operation, LLT: Toe operation - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 06:39:36 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 06:39:36 |
| Data point term sent to Coder | System | 27 Aug 2020 18:51:29 |
| User entered 'toe surgery' | (b) (4), (b) (6) (b) (4) (b) (4) | 27 Aug 2020 18:51:03 |

US3292320

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered 'un UNK 2005' | (b) (4), (b) (6) | 27 Aug 2020 18:51:03 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:25

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:51:03 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:25

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 18:51:03 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered 'un UNK 2005' | (b) (4), (b) (6) | 27 Aug 2020 18:51:03 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:25

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:51:03 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2005' | System | 27 Aug 2020 18:51:03 |

US3292320

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2005' | System | 27 Aug 2020 18:51:03 |

US3292320

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2005' | System | 27 Aug 2020 18:51:03 |

US3292320

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2005' | System | 27 Aug 2020 18:51:03 |

US3292320

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:52:25

Condition

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Nasal septum deviation, LLT: Deviated nasal septum - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Oct 2020 20:51:40 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Oct 2020 20:51:40 |
| Data point term sent to Coder | System | 22 Oct 2020 20:50:48 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Nasal septum deviation, LLT: Deviated nasal septum - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 00:50:14 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 00:50:14 |
| Data point term sent to Coder | System | 27 Aug 2020 18:51:32 |
| User entered 'deviated septun' | (b) (4), (b) (6) | 27 Aug 2020 18:51:20 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered 'un UNK 2017' | (b) (4), (b) (6) | 27 Aug 2020 18:51:20 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:52:25

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:51:20 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:52:25

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 18:51:20 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered 'un UNK 2017' | (b) (4), (b) (6) | 27 Aug 2020 18:51:20 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:52:25

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:51:20 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2017' | System | 27 Aug 2020 18:51:20 |

US3292320

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2017' | System | 27 Aug 2020 18:51:20 |

US3292320

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2017' | System | 27 Aug 2020 18:51:20 |

US3292320

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2017' | System | 27 Aug 2020 18:51:20 |

US3292320

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:52:25

Condition

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Oct 2020 20:51:40 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Oct 2020 20:51:40 |
| Data point term sent to Coder | System | 22 Oct 2020 20:50:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 27 Aug 2020 19:50:35 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 27 Aug 2020 19:50:35 |
| Data point term sent to Coder | System | 27 Aug 2020 18:52:34 |
| User entered 'hypertension' | (b) (4), (b) (6) | 27 Aug 2020 18:52:19 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered 'un UNK 2018' | (b) (4), (b) (6) | 27 Aug 2020 18:52:19 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:52:25

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:52:19 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:52:25

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 18:52:19 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 18:52:19 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:52:25

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:52:19 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2018' | System | 27 Aug 2020 18:52:19 |

US3292320

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2018' | System | 27 Aug 2020 18:52:19 |

US3292320

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Aug 2020 18:52:19 |

US3292320

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Aug 2020 18:52:19 |

US3292320

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:52:25

Condition

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Site specific injuries NEC, PT: Limb injury, LLT: Toe injury - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Oct 2020 20:51:40 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Oct 2020 20:51:40 |
| Data point term sent to Coder | System | 22 Oct 2020 20:50:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Site specific injuries NEC, PT: Limb injury, LLT: Toe injury - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 10:00:33 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 10:00:33 |
| Data point term sent to Coder | System | 27 Aug 2020 18:53:35 |
| User entered 'injury to left big toe' | (b) (4), (b) (6) | 27 Aug 2020 18:52:37 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered 'un UNK 2005' | (b) (4), (b) (6) | 27 Aug 2020 18:52:37 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:52:25

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:52:37 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:52:25

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 18:52:37 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered 'un UNK 2005' | (b) (4), (b) (6) | 27 Aug 2020 18:52:37 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:52:25

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:52:37 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2005' | System | 27 Aug 2020 18:52:37 |

US3292320

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2005' | System | 27 Aug 2020 18:52:37 |

US3292320

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2005' | System | 27 Aug 2020 18:52:37 |

US3292320

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2005' | System | 27 Aug 2020 18:52:37 |

US3292320

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:52:25

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User closed query 'Per source, start date of condition wa 2008. Please confirm and update eCRF if appropriate.' (Site from CRA). | (b) (4), (b) (6) | 06 Nov 2020 19:15:24 |
| Query 'Per source, start date of condition wa 2008. Please confirm and update eCRF if appropriate.' answered with 'updated' (Site from CRA). | Dawn Killian (b) (4) | 29 Oct 2020 16:41:56 |
| Query 'Please consider updating source with "spinal"' answered with 'updated' (Site from CRA). | Dawn Killian (b) (4) | 29 Oct 2020 16:41:53 |
| User opened query 'Per source, start date of condition wa 2008. Please confirm and update eCRF if appropriate.' (Site from CRA). | (b) (4), (b) (6) | 22 Oct 2020 20:52:32 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Spinal osteoarthritis - version MedDRA\\23.0. | Coder Import (b) (4) | 22 Oct 2020 20:51:40 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 22 Oct 2020 20:51:40 |
| User opened query 'Please consider updating source with "spinal"' (Site from CRA). | (b) (4), (b) (6) | 22 Oct 2020 20:51:18 |
| Data point term sent to Coder | System | 22 Oct 2020 20:50:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User closed query 'Per DM CLR: Please update the condition to include the location of OSTEOARTHRITIS (arms, Legs, Generalized, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM). | (b) (4), (b) (6) | 08 Oct 2020 14:40:05 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Spinal osteoarthritis - version MedDRA\\23.0. | Coder Import (b) (4) | 23 Sep 2020 15:53:38 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 23 Sep 2020 15:53:38 |

US3292320

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:52:25

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Query 'Per DM CLR: Please update the condition to include the location of OSTEOARTHRITIS (arms, Legs, Generalized, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'UPDATED' (Site from DM). | Victoria Hernandez (b) (4) | 23 Sep 2020 15:52:40 |
| Data point term sent to Coder | System | 23 Sep 2020 15:52:31 |
| Coding entries removed. | Victoria Hernandez (b) (4) | 23 Sep 2020 15:52:27 |
| User entered 'SPINAL OSTEOARTHRITIS' reason for change: Data Entry Error | Victoria Hernandez (b) (4) | 23 Sep 2020 15:52:27 |
| User opened query 'Per DM CLR: Please update the condition to include the location of OSTEOARTHRITIS (arms, Legs, Generalized, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. | (b) (4), (b) (6) | 09 Sep 2020 19:05:25 |
| ' (Site from DM). | | |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 19:50:44 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 19:50:44 |
| Data point term sent to Coder | System | 27 Aug 2020 18:54:37 |
| User entered 'osteoarthritis' | (b) (4), (b) (6) | 27 Aug 2020 18:53:46 |

US3292320

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:15:28 |
| DataPoint Un-verified. | Dawn Killian (b) (4) | 29 Oct 2020 16:41:48 |
| User entered 'UN UNK 2008' reason for change: | (b) (4) | |
| Data Entry Error | Dawn Killian (b) (4) | 29 Oct 2020 16:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 18:53:46 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:52:25

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:15:30 |
| DataPoint Un-verified. | Dawn Killian (b) (4) | 29 Oct 2020 16:41:48 |
| User entered '0' reason for change: Data Entry Error | (b) (4) | 29 Oct 2020 16:41:48 |
| DataPoint Verified. | Dawn Killian (b) (4) | 22 Oct 2020 20:50:46 |
| User entered '1' | (b) (4), (b) (6) | 27 Aug 2020 18:53:46 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:52:25

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 23 Sep 2020 15:52:32 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 23 Sep 2020 15:52:32 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Victoria Hernandez (b) (4) | 23 Sep 2020 15:52:32 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 27 Aug 2020 18:53:46 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 18:53:46 |

US3292320

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 18:53:46 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:52:25

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:53:46 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2008' | System | 29 Oct 2020 16:41:48 |
| User entered empty. | System | 27 Aug 2020 18:53:46 |

US3292320

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2008' | System | 29 Oct 2020 16:41:48 |
| User entered empty. | System | 27 Aug 2020 18:53:46 |

US3292320

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Aug 2020 18:53:46 |

US3292320

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Aug 2020 18:53:46 |

US3292320

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:52:25

Condition

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User closed query 'Con Med for Low Testosterone treatment has been removed from eCRF but another treatment for this condition is listed in source. Please reconcile.' (Site from CRA). | (b) (4), (b) (6) | 06 Nov 2020 19:16:07 |
| Query 'Con Med for Low Testosterone treatment has been removed from eCRF but another treatment for this condition is listed in source. Please reconcile.' answered with 'Treatment has been reactivated as per source.' (Site from CRA). | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:09:41 |
| User opened query 'Con Med for Low Testosterone treatment has been removed from eCRF but another treatment for this condition is listed in source. Please reconcile.' (Site from CRA). | (b) (4), (b) (6) | 22 Oct 2020 21:01:51 |
| User coded data point as SOC: Investigations, HLGT: Endocrine investigations (incl sex hormones), HLT: Reproductive hormone analyses, PT: Blood testosterone decreased, LLT: Testosterone low - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Oct 2020 20:51:40 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Oct 2020 20:51:40 |
| Data point term sent to Coder | System | 22 Oct 2020 20:50:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User coded data point as SOC: Investigations, HLGT: Endocrine investigations (incl sex hormones), HLT: Reproductive hormone analyses, PT: Blood testosterone decreased, LLT: Testosterone low - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 27 Aug 2020 19:50:45 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 27 Aug 2020 19:50:45 |
| Data point term sent to Coder | System | 27 Aug 2020 18:54:39 |
| User entered 'low testosterone' | (b) (4), (b) (6) | 27 Aug 2020 18:54:02 |

US3292320

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered 'un UNK 2018' | (b) (4), (b) (6) | 27 Aug 2020 18:54:02 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:52:25

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:54:02 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:52:25

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 18:54:02 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 18:54:02 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:52:25

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:50:46 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:54:02 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2018' | System | 27 Aug 2020 18:54:02 |

US3292320

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2018' | System | 27 Aug 2020 18:54:02 |

US3292320

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Aug 2020 18:54:02 |

US3292320

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Aug 2020 18:54:02 |

US3292320

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:52:25

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:16:42 |
| User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis contact, LLT: Adhesive tape allergy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 22:28:27 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 22:28:27 |
| Data point term sent to Coder | System | 05 Nov 2020 22:28:00 |
| User entered 'Adhesive Allergy' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:27:19 |

US3292320

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:16:44 |
| User entered 'UN UNK 2005' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:27:19 |

US3292320

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:52:25

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:16:45 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:27:19 |

US3292320

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:52:25

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:16:47 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:27:19 |

US3292320

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:16:49 |
| User entered 'UN UNK 2005' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:27:19 |

US3292320

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:52:25

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:16:51 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:27:19 |

US3292320

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2005' | System | 05 Nov 2020 22:27:19 |

US3292320

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2005' | System | 05 Nov 2020 22:27:19 |

US3292320

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2005' | System | 05 Nov 2020 22:27:19 |

US3292320

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2005' | System | 05 Nov 2020 22:27:19 |

US3292320

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:52:25

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:17:44 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 22:29:31 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 22:29:31 |
| Data point term sent to Coder | System | 05 Nov 2020 22:29:01 |
| User entered 'Low Back Pain' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:28:08 |

US3292320

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:17:46 |
| User entered 'UN UNK 1991' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:28:08 |

US3292320

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:52:25

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:17:48 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:28:08 |

US3292320

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:52:25

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:17:50 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:28:08 |

US3292320

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:17:52 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:28:08 |

US3292320

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:52:25

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:17:53 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:28:08 |

US3292320

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 1991' | System | 05 Nov 2020 22:28:08 |

US3292320

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1991' | System | 05 Nov 2020 22:28:08 |

US3292320

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 22:28:08 |

US3292320

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 22:28:08 |

US3292320

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:52:25

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:18:11 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Benign neoplasms gastrointestinal, HLT: Benign neoplasms gastrointestinal (excl oral cavity), PT: Large intestine polyp, LLT: Colonic polyp - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 22:44:30 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 22:44:30 |
| Data point term sent to Coder | System | 05 Nov 2020 22:29:01 |
| User entered 'Colonic Polyp' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:28:34 |

US3292320

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:18:13 |
| User entered 'UN UNK 2016' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:28:34 |

US3292320

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:52:25

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:18:14 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:28:34 |

US3292320

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:52:25

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:18:17 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:28:34 |

US3292320

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:18:20 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:28:34 |

US3292320

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:52:25

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:18:21 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:28:34 |

US3292320

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2016' | System | 05 Nov 2020 22:28:34 |

US3292320

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2016' | System | 05 Nov 2020 22:28:34 |

US3292320

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 22:28:34 |

US3292320

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 22:28:34 |

US3292320

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:52:25

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:18:34 |
| User coded data point as SOC: Endocrine disorders, HLGT: Endocrine disorders of gonadal function, HLT: Endocrine abnormalities of gonadal function NEC, PT: Hypogonadism, LLT: Hypogonadism - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 22:29:30 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 22:29:30 |
| Data point term sent to Coder | System | 05 Nov 2020 22:29:02 |
| User entered 'Hypogonadism' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:29:00 |

US3292320

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:18:36 |
| User entered 'un UNK 2018' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:29:00 |

US3292320

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:52:25

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:18:37 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:29:00 |

US3292320

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:52:25

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:18:39 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:29:00 |

US3292320

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:18:42 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:29:00 |

US3292320

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:52:25

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:18:45 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:29:00 |

US3292320

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2018' | System | 05 Nov 2020 22:29:00 |

US3292320

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2018' | System | 05 Nov 2020 22:29:00 |

US3292320

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 22:29:00 |

US3292320

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 22:29:00 |

US3292320

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:52:25

[Condition](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:18:56 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 22:31:28 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 22:31:28 |
| Data point term sent to Coder | System | 05 Nov 2020 22:31:08 |
| User entered 'Obstructive Sleep Apnea' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:30:45 |

US3292320

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:19:00 |
| User entered 'un UNK 2008' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:30:45 |

US3292320

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:52:25

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:19:02 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:30:45 |

US3292320

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:52:25

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:19:05 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:30:45 |

US3292320

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:19:07 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:30:45 |

US3292320

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:52:25

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:19:09 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:30:45 |

US3292320

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2008' | System | 05 Nov 2020 22:30:45 |

US3292320

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2008' | System | 05 Nov 2020 22:30:45 |

US3292320

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 22:30:45 |

US3292320

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 22:30:45 |

US3292320

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:52:25

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:19:22 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in joint involving shoulder region - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 06 Nov 2020 05:48:29 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 06 Nov 2020 05:48:29 |
| Data point term sent to Coder | System | 05 Nov 2020 22:32:08 |
| User entered 'R Shoulder joint pain' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:31:08 |

US3292320

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:19:24 |
| User entered 'un UNK 2004' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:31:08 |

US3292320

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:52:25

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:19:26 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:31:08 |

US3292320

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:52:25

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:19:27 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:31:08 |

US3292320

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:19:29 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:31:08 |

US3292320

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:52:25

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:19:31 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:31:08 |

US3292320

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2004' | System | 05 Nov 2020 22:31:08 |

US3292320

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2004' | System | 05 Nov 2020 22:31:08 |

US3292320

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 22:31:08 |

US3292320

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 22:31:08 |

US3292320

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:52:25

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:19:49 |
| User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 22:32:47 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 22:32:47 |
| Data point term sent to Coder | System | 05 Nov 2020 22:32:08 |
| User entered 'Constipation' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:31:52 |

US3292320

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:19:50 |
| User entered 'un UNK 2018' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:31:52 |

US3292320

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:52:25

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:19:52 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:31:52 |

US3292320

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:52:25

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:19:53 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:31:52 |

US3292320

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:19:55 |
| User entered 'un UNK 2018' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:31:52 |

US3292320

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:52:25

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:19:57 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:31:52 |

US3292320

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2018' | System | 05 Nov 2020 22:31:52 |

US3292320

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2018' | System | 05 Nov 2020 22:31:52 |

US3292320

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2018' | System | 05 Nov 2020 22:31:52 |

US3292320

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2018' | System | 05 Nov 2020 22:31:52 |

US3292320

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:52:25

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:20:05 |
| 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) | 05 Nov 2020 22:34:32 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 22:34:32 |
| Data point term sent to Coder | System | 05 Nov 2020 22:33:11 |
| User entered 'Hyperlipidemia' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:32:18 |

US3292320

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:20:06 |
| User entered 'un UNK 2018' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:32:18 |

US3292320

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:52:25

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:20:08 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:32:18 |

US3292320

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:52:25

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:20:10 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:32:18 |

US3292320

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:20:12 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:32:18 |

US3292320

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:52:25

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:20:13 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:32:18 |

US3292320

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2018' | System | 05 Nov 2020 22:32:18 |

US3292320

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2018' | System | 05 Nov 2020 22:32:18 |

US3292320

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 22:32:18 |

US3292320

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 22:32:18 |

US3292320

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:52:25

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:20:19 |
| User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Cervical spinal cord and nerve root disorders, PT: Cervical radiculopathy, LLT: Cervical radiculopathy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 22:34:32 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 22:34:32 |
| Data point term sent to Coder | System | 05 Nov 2020 22:33:13 |
| User entered 'Cervical Radiculopathy' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:32:49 |

US3292320

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:20:27 |
| User entered 'un UNK 2008' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:32:49 |

US3292320

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:52:25

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:20:29 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:32:49 |

US3292320

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:52:25

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:20:30 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:32:49 |

US3292320

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:20:32 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:32:49 |

US3292320

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:52:25

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:20:34 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:32:49 |

US3292320

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2008' | System | 05 Nov 2020 22:32:49 |

US3292320

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2008' | System | 05 Nov 2020 22:32:49 |

US3292320

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 22:32:49 |

US3292320

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 22:32:49 |

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:53:52 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 18:54:40 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:53:52 |
| User entered '25 Aug 2020' | (b) (4), (b) (6) | 27 Aug 2020 18:54:40 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:53:52 |
| User entered '15:16' | (b) (4), (b) (6) | 27 Aug 2020 18:54:40 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 15:16' | System | 27 Aug 2020 18:54:40 |

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Height \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:53:52 |
| User entered '175.5' cm | (b) (4), (b) (6) | 27 Aug 2020 18:54:40 |
| DataPoint set to visible. | System | 25 Aug 2020 21:39:37 |

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

Weight (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:53:52 |
| User entered '95.6' kg | (b) (4), (b) (6) | 27 Aug 2020 18:54:40 |
| DataPoint set to visible. | System | 25 Aug 2020 21:39:37 |

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

BMI (xxx.x)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: User entered '31.03871' | System | 17 Sep 2020 00:02:45 |
| User entered '31.0' | System | 27 Aug 2020 18:54:40 |
| DataPoint set to visible. | System | 25 Aug 2020 21:39:37 |

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|--------|----------------------|
| User entered 'kg/m2' | System | 27 Aug 2020 18:54:40 |
| DataPoint set to visible. | System | 25 Aug 2020 21:39:37 |

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:53:52 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 27 Aug 2020 18:54:40 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:53:52 |
| User entered 'Other (Other)' | (b) (4), (b) (6) | 27 Aug 2020 18:54:40 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[If Other, specify](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:53:52 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 27 Aug 2020 18:54:40 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:53:52 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 27 Aug 2020 18:54:40 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 27 Aug 2020 18:54:40 |

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:53:52 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 27 Aug 2020 18:54:40 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 27 Aug 2020 18:54:40 |

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:53:52 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 27 Aug 2020 18:54:40 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 27 Aug 2020 18:54:40 |

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:53:52 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 27 Aug 2020 18:54:40 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 27 Aug 2020 18:54:40 |

US3292320

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:25

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:53:57 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 18:54:48 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:25

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:53:57 |
| User entered '25 Aug 2020' | (b) (4), (b) (6) | 27 Aug 2020 18:54:48 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:25

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:54:12 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 18:55:27 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:25

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:54:12 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 18:55:27 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:25

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) | 22 Oct 2020 20:54:12 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 18:55:27 |

US3292320

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:25

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:54:12 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 18:55:27 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:25

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:54:12 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 18:55:27 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:25

[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) | 22 Oct 2020 20:54:12 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 18:55:27 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:25

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) | 22 Oct 2020 20:54:12 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 18:55:27 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Risk of Exposure

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Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:54:12 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 18:55:27 |

US3292320

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:25

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:54:12 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 18:55:27 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:25

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) | 22 Oct 2020 20:54:12 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 18:55:27 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:25

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) | 22 Oct 2020 20:54:12 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 18:55:27 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:25

[Other](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:54:12 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 18:55:27 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:25

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:54:12 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 18:55:27 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:25

No Risk Identified

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered 'I' | (b) (4), (b) (6) | 27 Aug 2020 18:55:27 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:25

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:54:12 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:55:27 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:25

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) | 22 Oct 2020 20:54:12 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:55:27 |

US3292320

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:25

[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) | 22 Oct 2020 20:54:12 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:55:27 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:25

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) | 22 Oct 2020 20:54:12 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:55:27 |

US3292320

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:25

[Resides in a single family home](#) (i.e., detached housing)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:54:12 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:55:27 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:25

Other

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 18:55:27 |
| | | |
| | | |

US3292320

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:25

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:54:12 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 18:55:27 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:54:29 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 18:57:44 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:54:29 |
| User entered '25 Aug 2020' | (b) (4), (b) (6) | 27 Aug 2020 18:57:44 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:54:29 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 27 Aug 2020 18:57:44 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'VISIT1' | System | 27 Aug 2020 18:57:44 |

US3292320

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:52:25

What was the date of randomization? (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:54:33 |
| User entered '25 AUG 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 25 Aug 2020 21:19:17 |

US3292320

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:52:25

[What was the participant's randomization number?](#)

| Audit | User | Time (GMT) |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:54:33 |
| User entered '108491' | RWS_ENDPOINT ENDPOINT (b) (4) | 25 Aug 2020 21:19:17 |

US3292320

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:52:25

[In what Cohort was the participant enrolled?](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:54:33 |
| User entered '>=18 and <65 years and not at risk (1)' | RWS_ENDPOINT ENDPOINT (b) (4) | 25 Aug 2020 21:19:17 |

US3292320

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:52:25

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) | 22 Oct 2020 20:54:33 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 18:58:16 |

US3292320

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:52:25

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) | 22 Oct 2020 20:54:33 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 18:58:16 |

US3292320

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:52:25

Severe obesity (body mass index > or = 40kg/m2

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:54:33 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 18:58:16 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:52:25

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:54:33 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 18:58:16 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:52:25

[Liver Disease](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:54:33 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 18:58:16 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:52:25

[Human Immunodeficiency Virus \(HIV\) infection](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: DataPoint set to visible. | System | 19 Sep 2020 07:56:01 |
| Amendment Manager inserted this DataPoint. | System | 19 Sep 2020 07:56:00 |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:52:25

[Height](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:52:25

[Weight](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:52:25

[Height](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:52:25

[Weight](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered '25 Aug 2020' | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered '15:22' | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 15:22' | System | 27 Aug 2020 19:32:01 |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered '036.4' C | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered '075' | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 27 Aug 2020 19:32:01 |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered '016' | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 27 Aug 2020 19:32:01 |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered '149' | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 27 Aug 2020 19:32:01 |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered '089' | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 27 Aug 2020 19:32:01 |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:52:25

[Height](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:52:25

[Weight](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered '25 Aug 2020' | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered '17:06' | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 17:06' | System | 27 Aug 2020 19:32:01 |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered '36.6' C | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered '67' | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 27 Aug 2020 19:32:01 |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered '16' | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 27 Aug 2020 19:32:01 |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered '128' | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 27 Aug 2020 19:32:01 |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:20 |
| User entered '80' | (b) (4), (b) (6) | 27 Aug 2020 19:32:01 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 27 Aug 2020 19:32:01 |

US3292320

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:25

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:59 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 19:32:07 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:25

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:55:59 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 19:32:07 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:25

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:56:03 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Aug 2020 21:40:04 |

US3292320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:25

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:56:03 |
| User entered empty. | (b) (4), (b) (6) | 25 Aug 2020 21:40:04 |

US3292320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:25

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) | 22 Oct 2020 20:56:03 |
| User entered empty. | (b) (4), (b) (6) | 25 Aug 2020 21:40:04 |

US3292320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:25

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:25

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:56:03 |
| User entered '25 Aug 2020' | (b) (4), (b) (6) | 25 Aug 2020 21:40:04 |

US3292320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:25

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:56:03 |
| User entered '16:31' | (b) (4), (b) (6) | 25 Aug 2020 21:40:04 |

US3292320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:25

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 16:31' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:25

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:56:03 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4), (b) (6) | 25 Aug 2020 21:40:04 |

US3292320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:25

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:56:03 |
| User entered 'ONCE' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:25

[What was the route of administration for the study treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:25

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:56:45 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 19:33:34 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:25

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:56:45 |
| User entered '25 Aug 2020' | (b) (4), (b) (6) | 27 Aug 2020 19:33:34 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:25

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:56:45 |
| User entered '15:29' | (b) (4), (b) (6) | 27 Aug 2020 19:33:34 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:25

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 15:29' | System | 27 Aug 2020 19:33:34 |

US3292320

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:52:25

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:56:51 |
| User entered '25 Aug 2020' | (b) (4), (b) (6) | 27 Aug 2020 19:33:47 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:52:25

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | (b) (4), (b) (6) | 27 Aug 2020 19:33:47 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:52:25

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:56:51 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 19:33:47 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:52:25

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:56:51 |
| User entered '15:45' | (b) (4), (b) (6) | 27 Aug 2020 19:33:47 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:52:25

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 15:45' | System | 27 Aug 2020 19:33:47 |

US3292320

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:52:25

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | (b) (4), (b) (6) | 27 Aug 2020 19:33:47 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:52:25

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:56:51 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 19:33:47 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:52:25

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:56:51 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 19:33:47 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:52:25

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Aug 2020 19:33:47 |

US3292320

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 19:33:52 |
| | | |
| | | |

US3292320

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 27 Aug 2020 19:33:52 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:08:30', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6b342c84-b060-44d9-9a38-528ea5ec4438' | System | 25 Aug 2020 22:09:59 |
| User entered 'Yes (Y)' | System | 25 Aug 2020 22:09:59 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:09:30', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6b342c84-b060-44d9-9a38-528ea5ec4438' | System | 25 Aug 2020 22:09:59 |
| User entered '97.9' | System | 25 Aug 2020 22:09:59 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:09:55', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6b342c84-b060-44d9-9a38-528ea5ec4438' | System | 25 Aug 2020 22:09:59 |
| User entered 'No (N)' | System | 25 Aug 2020 22:09:59 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:09:58', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6b342c84-b060-44d9-9a38-528ea5ec4438' | System | 25 Aug 2020 22:09:59 |
| User entered '25 Aug 2020 17:09' | System | 25 Aug 2020 22:09:59 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 16:51' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 19:21' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 1, after vaccination (at home)' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:29:09', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'fc641203-5b9f-4fa9-9807-7098dba03b92' | System | 26 Aug 2020 02:31:59 |
| User entered 'Yes (Y)' | System | 26 Aug 2020 02:31:59 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:31:50', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'fc641203-5b9f-4fa9-9807-7098dba03b92' | System | 26 Aug 2020 02:31:59 |
| User entered '98.7' | System | 26 Aug 2020 02:31:59 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:31:54', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'fc641203-5b9f-4fa9-9807-7098dba03b92' | System | 26 Aug 2020 02:31:59 |
| User entered 'No (N)' | System | 26 Aug 2020 02:31:59 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:31:56', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'fc641203-5b9f-4fa9-9807-7098dba03b92' | System | 26 Aug 2020 02:31:59 |
| User entered '25 Aug 2020 21:31' | System | 26 Aug 2020 02:31:59 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 20:16' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 11:59' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 2' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:25

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:07', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '699e1356-2c6d-4a87-8be0-99c21967632a' | System | 27 Aug 2020 05:06:27 |
| User entered 'Yes (Y)' | System | 27 Aug 2020 05:06:27 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:25

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:15', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '699e1356-2c6d-4a87-8be0-99c21967632a' | System | 27 Aug 2020 05:06:27 |
| User entered '98.7' | System | 27 Aug 2020 05:06:27 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:19', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '699e1356-2c6d-4a87-8be0-99c21967632a' | System | 27 Aug 2020 05:06:27 |
| User entered 'No (N)' | System | 27 Aug 2020 05:06:27 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:26', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '699e1356-2c6d-4a87-8be0-99c21967632a' | System | 27 Aug 2020 05:06:27 |
| User entered '27 Aug 2020 00:06' | System | 27 Aug 2020 05:06:27 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 12:00' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 11:59' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 3' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:25

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:25', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '2408a021-04d4-4f34-bd1f-c499f35a2fe0' | System | 28 Aug 2020 07:00:50 |
| User entered 'Yes (Y)' | System | 28 Aug 2020 07:00:50 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:25

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:38', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '2408a021-04d4-4f34-bd1f-c499f35a2fe0' | System | 28 Aug 2020 07:00:50 |
| User entered '98.5' | System | 28 Aug 2020 07:00:50 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:42', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '2408a021-04d4-4f34-bd1f-c499f35a2fe0' | System | 28 Aug 2020 07:00:50 |
| User entered 'No (N)' | System | 28 Aug 2020 07:00:50 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:46', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '2408a021-04d4-4f34-bd1f-c499f35a2fe0' | System | 28 Aug 2020 07:00:50 |
| User entered '28 Aug 2020 02:00' | System | 28 Aug 2020 07:00:50 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 12:00' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Aug 2020 11:59' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 4' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:25

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:32:37', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9a819c4b-9000-4f0c-9303-d9e478c2f3aa' | System | 29 Aug 2020 05:33:12 |
| User entered 'Yes (Y)' | System | 29 Aug 2020 05:33:12 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:25

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:01', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9a819c4b-9000-4f0c-9303-d9e478c2f3aa' | System | 29 Aug 2020 05:33:12 |
| User entered '98.7' | System | 29 Aug 2020 05:33:12 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:04', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9a819c4b-9000-4f0c-9303-d9e478c2f3aa' | System | 29 Aug 2020 05:33:12 |
| User entered 'No (N)' | System | 29 Aug 2020 05:33:12 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:07', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9a819c4b-9000-4f0c-9303-d9e478c2f3aa' User entered '29 Aug 2020 00:33' | System | 29 Aug 2020 05:33:12 |
| | System | 29 Aug 2020 05:33:12 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Aug 2020 12:00' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Aug 2020 11:59' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 5' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:25

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:30:19', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8d41e26e-0f6c-4e80-a64c-af02c62376b7' | System | 30 Aug 2020 03:30:34 |
| User entered 'Yes (Y)' | System | 30 Aug 2020 03:30:34 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:25

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:30:24', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8d41e26e-0f6c-4e80-a64c-af02c62376b7' | System | 30 Aug 2020 03:30:34 |
| User entered '96.7' | System | 30 Aug 2020 03:30:34 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:30:27', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8d41e26e-0f6c-4e80-a64c-af02c62376b7' | System | 30 Aug 2020 03:30:34 |
| User entered 'No (N)' | System | 30 Aug 2020 03:30:34 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:30:31', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8d41e26e-0f6c-4e80-a64c-af02c62376b7' | System | 30 Aug 2020 03:30:34 |
| User entered '29 Aug 2020 22:30' | System | 30 Aug 2020 03:30:34 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Aug 2020 12:00' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '30 Aug 2020 11:59' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 6' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:25

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:08', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a3609f78-04ae-43b4-a2b1-728ce02a9a37' | System | 30 Aug 2020 18:14:21 |
| User entered 'Yes (Y)' | System | 30 Aug 2020 18:14:21 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:25

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:13', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a3609f78-04ae-43b4-a2b1-728ce02a9a37' | System | 30 Aug 2020 18:14:21 |
| User entered '97.4' | System | 30 Aug 2020 18:14:21 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:15', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a3609f78-04ae-43b4-a2b1-728ce02a9a37' | System | 30 Aug 2020 18:14:21 |
| User entered 'No (N)' | System | 30 Aug 2020 18:14:21 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:17', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a3609f78-04ae-43b4-a2b1-728ce02a9a37' | System | 30 Aug 2020 18:14:21 |
| User entered '30 Aug 2020 13:14' | System | 30 Aug 2020 18:14:21 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '30 Aug 2020 12:00' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 11:59' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 7' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:25

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:41:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '4faa2baf-6217-4783-92c8-2ae454b9ca65' | System | 01 Sep 2020 03:41:13 |
| User entered 'Yes (Y)' | System | 01 Sep 2020 03:41:13 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:25

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:41:05', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '4faa2baf-6217-4783-92c8-2ae454b9ca65' | System | 01 Sep 2020 03:41:13 |
| User entered '97.4' | System | 01 Sep 2020 03:41:13 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:41:08', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '4faa2baf-6217-4783-92c8-2ae454b9ca65' | System | 01 Sep 2020 03:41:13 |
| User entered 'No (N)' | System | 01 Sep 2020 03:41:13 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:41:11', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '4faa2baf-6217-4783-92c8-2ae454b9ca65' | System | 01 Sep 2020 03:41:13 |
| User entered '31 Aug 2020 22:41' | System | 01 Sep 2020 03:41:13 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 12:00' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '01 Sep 2020 11:59' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:06:32', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '0596171c-1b9a-4029-bf6d-ab700bdd82bc' | System | 25 Aug 2020 22:07:04 |
| User entered 'None (1)' | System | 25 Aug 2020 22:07:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:06:35', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '0596171c-1b9a-4029-bf6d-ab700bdd82bc' | System | 25 Aug 2020 22:07:04 |
| User entered 'No (N)' | System | 25 Aug 2020 22:07:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:06:43', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '0596171c-1b9a-4029-bf6d-ab700bdd82bc' | System | 25 Aug 2020 22:07:04 |
| User entered 'No (N)' | System | 25 Aug 2020 22:07:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:06:50', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '0596171c-1b9a-4029-bf6d-ab700bdd82bc' | System | 25 Aug 2020 22:07:04 |
| User entered 'None (1)' | System | 25 Aug 2020 22:07:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:07:00', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '0596171c-1b9a-4029-bf6d-ab700bdd82bc' | System | 25 Aug 2020 22:07:04 |
| User entered '25 Aug 2020 17:07' | System | 25 Aug 2020 22:07:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 16:51' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 19:21' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 1, after vaccination (at home)' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:05', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'f613da89-eef5-4967-83a4-91eb6d6089f6' | System | 26 Aug 2020 02:32:21 |
| User entered 'None (1)' | System | 26 Aug 2020 02:32:21 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:09', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'f613da89-eef5-4967-83a4-91eb6d6089f6' | System | 26 Aug 2020 02:32:21 |
| User entered 'No (N)' | System | 26 Aug 2020 02:32:21 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:12', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'f613da89-eef5-4967-83a4-91eb6d6089f6' | System | 26 Aug 2020 02:32:21 |
| User entered 'No (N)' | System | 26 Aug 2020 02:32:21 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:17', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'f613da89-eef5-4967-83a4-91eb6d6089f6' | System | 26 Aug 2020 02:32:21 |
| User entered 'None (1)' | System | 26 Aug 2020 02:32:21 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:20', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'f613da89-eef5-4967-83a4-91eb6d6089f6' | System | 26 Aug 2020 02:32:21 |
| User entered '25 Aug 2020 21:32' | System | 26 Aug 2020 02:32:21 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 20:16' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 11:59' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 2' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:25

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:30', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '239def3c-5b16-4fa5-a09a-5ea915c4f1d1' | System | 27 Aug 2020 05:06:47 |
| User entered 'None (1)' | System | 27 Aug 2020 05:06:47 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:33', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '239def3c-5b16-4fa5-a09a-5ea915c4f1d1' | System | 27 Aug 2020 05:06:47 |
| User entered 'No (N)' | System | 27 Aug 2020 05:06:47 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:38', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '239def3c-5b16-4fa5-a09a-5ea915c4f1d1' | System | 27 Aug 2020 05:06:47 |
| User entered 'No (N)' | System | 27 Aug 2020 05:06:47 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:42', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '239def3c-5b16-4fa5-a09a-5ea915c4f1d1' | System | 27 Aug 2020 05:06:47 |
| User entered 'None (1)' | System | 27 Aug 2020 05:06:47 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:45', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '239def3c-5b16-4fa5-a09a-5ea915c4f1d1' | System | 27 Aug 2020 05:06:47 |
| User entered '27 Aug 2020 00:06' | System | 27 Aug 2020 05:06:47 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 12:00' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 11:59' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 3' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:25

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:05', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6166d662-2fb1-4ec5-ad44-a30bd1b292d3' | System | 28 Aug 2020 07:00:23 |
| User entered 'None (1)' | System | 28 Aug 2020 07:00:23 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:08', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6166d662-2fb1-4ec5-ad44-a30bd1b292d3' | System | 28 Aug 2020 07:00:23 |
| User entered 'No (N)' | System | 28 Aug 2020 07:00:23 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:11', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6166d662-2fb1-4ec5-ad44-a30bd1b292d3' | System | 28 Aug 2020 07:00:23 |
| User entered 'No (N)' | System | 28 Aug 2020 07:00:23 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:14', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6166d662-2fb1-4ec5-ad44-a30bd1b292d3' | System | 28 Aug 2020 07:00:23 |
| User entered 'None (1)' | System | 28 Aug 2020 07:00:23 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:19', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6166d662-2fb1-4ec5-ad44-a30bd1b292d3' | System | 28 Aug 2020 07:00:23 |
| User entered '28 Aug 2020 02:00' | System | 28 Aug 2020 07:00:23 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 12:00' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Aug 2020 11:59' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 4' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:12', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c3212415-d606-4f47-bf6d-1cdf696d98d9' | System | 29 Aug 2020 05:33:28 |
| User entered 'None (1)' | System | 29 Aug 2020 05:33:28 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:15', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c3212415-d606-4f47-bf6d-1cdf696d98d9' | System | 29 Aug 2020 05:33:28 |
| User entered 'No (N)' | System | 29 Aug 2020 05:33:28 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:18', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c3212415-d606-4f47-bf6d-1cdf696d98d9' | System | 29 Aug 2020 05:33:28 |
| User entered 'No (N)' | System | 29 Aug 2020 05:33:28 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:24', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c3212415-d606-4f47-bf6d-1cdf696d98d9' | System | 29 Aug 2020 05:33:28 |
| User entered 'None (1)' | System | 29 Aug 2020 05:33:28 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:27', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c3212415-d606-4f47-bf6d-1cdf696d98d9' | System | 29 Aug 2020 05:33:28 |
| User entered '29 Aug 2020 00:33' | System | 29 Aug 2020 05:33:28 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Aug 2020 12:00' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Aug 2020 11:59' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 5' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:30:44', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'f98cd639-475a-4619-87d4-041a2abcd7b9' | System | 30 Aug 2020 03:30:56 |
| User entered 'None (1)' | System | 30 Aug 2020 03:30:56 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:30:46', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'f98cd639-475a-4619-87d4-041a2abcd7b9' | System | 30 Aug 2020 03:30:56 |
| User entered 'No (N)' | System | 30 Aug 2020 03:30:56 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:30:48', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'f98cd639-475a-4619-87d4-041a2abcd7b9' | System | 30 Aug 2020 03:30:56 |
| User entered 'No (N)' | System | 30 Aug 2020 03:30:56 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:30:51', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'f98cd639-475a-4619-87d4-041a2abcd7b9' | System | 30 Aug 2020 03:30:56 |
| User entered 'None (1)' | System | 30 Aug 2020 03:30:56 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:30:53', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'f98cd639-475a-4619-87d4-041a2abcd7b9' | System | 30 Aug 2020 03:30:56 |
| User entered '29 Aug 2020 22:30' | System | 30 Aug 2020 03:30:56 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Aug 2020 12:00' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '30 Aug 2020 11:59' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 6' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:20', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '778d3237-87a2-44db-8733-3b912c3e55fc' | System | 30 Aug 2020 18:14:34 |
| User entered 'None (1)' | System | 30 Aug 2020 18:14:34 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:22', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '778d3237-87a2-44db-8733-3b912c3e55fc' | System | 30 Aug 2020 18:14:34 |
| User entered 'No (N)' | System | 30 Aug 2020 18:14:34 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:23', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '778d3237-87a2-44db-8733-3b912c3e55fc' | System | 30 Aug 2020 18:14:34 |
| User entered 'No (N)' | System | 30 Aug 2020 18:14:34 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:25', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '778d3237-87a2-44db-8733-3b912c3e55fc' | System | 30 Aug 2020 18:14:34 |
| User entered 'None (1)' | System | 30 Aug 2020 18:14:34 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:27', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '778d3237-87a2-44db-8733-3b912c3e55fc' | System | 30 Aug 2020 18:14:34 |
| User entered '30 Aug 2020 13:14' | System | 30 Aug 2020 18:14:34 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '30 Aug 2020 12:00' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 11:59' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 7' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:25

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:41:14', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '455c509b-b3bc-494e-9de9-7e7ffd0fe04c' | System | 01 Sep 2020 03:42:16 |
| User entered 'None (1)' | System | 01 Sep 2020 03:42:16 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:41:17', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '455c509b-b3bc-494e-9de9-7e7ffd0fe04c' | System | 01 Sep 2020 03:42:16 |
| User entered 'No (N)' | System | 01 Sep 2020 03:42:16 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:41:19', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '455c509b-b3bc-494e-9de9-7e7ffd0fe04c' | System | 01 Sep 2020 03:42:16 |
| User entered 'No (N)' | System | 01 Sep 2020 03:42:16 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:41:21', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '455c509b-b3bc-494e-9de9-7e7ffd0fe04c' | System | 01 Sep 2020 03:42:16 |
| User entered 'None (1)' | System | 01 Sep 2020 03:42:16 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:42:14', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '455c509b-b3bc-494e-9de9-7e7ffd0fe04c' | System | 01 Sep 2020 03:42:16 |
| User entered '31 Aug 2020 22:42' | System | 01 Sep 2020 03:42:16 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 12:00' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '01 Sep 2020 11:59' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:10:07', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '07bc4122-acde-42c9-9719-d4c725f8eaf4' | System | 25 Aug 2020 22:10:34 |
| User entered 'None (0)' | System | 25 Aug 2020 22:10:34 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:10:11', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '07bc4122-acde-42c9-9719-d4c725f8eaf4' | System | 25 Aug 2020 22:10:34 |
| User entered 'None (0)' | System | 25 Aug 2020 22:10:34 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:10:16', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '07bc4122-acde-42c9-9719-d4c725f8eaf4' | System | 25 Aug 2020 22:10:34 |
| User entered 'None (0)' | System | 25 Aug 2020 22:10:34 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:10:19', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '07bc4122-acde-42c9-9719-d4c725f8eaf4' | System | 25 Aug 2020 22:10:34 |
| User entered 'None (0)' | System | 25 Aug 2020 22:10:34 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:10:22', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '07bc4122-acde-42c9-9719-d4c725f8eaf4' | System | 25 Aug 2020 22:10:34 |
| User entered 'None (0)' | System | 25 Aug 2020 22:10:34 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:10:24', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '07bc4122-acde-42c9-9719-d4c725f8eaf4' | System | 25 Aug 2020 22:10:34 |
| User entered 'None (0)' | System | 25 Aug 2020 22:10:34 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:10:28', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '07bc4122-acde-42c9-9719-d4c725f8eaf4' | System | 25 Aug 2020 22:10:34 |
| User entered 'No (N)' | System | 25 Aug 2020 22:10:34 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T17:10:31', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '07bc4122-acde-42c9-9719-d4c725f8eaf4' | System | 25 Aug 2020 22:10:34 |
| User entered '25 Aug 2020 17:10' | System | 25 Aug 2020 22:10:34 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 16:51' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 19:21' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 1, after vaccination (at home)' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:26', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '04eab155-80d2-4222-a42d-07fff36ebeed' | System | 26 Aug 2020 02:32:58 |
| User entered 'None (0)' | System | 26 Aug 2020 02:32:58 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:29', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '04eab155-80d2-4222-a42d-07fff36ebeed' | System | 26 Aug 2020 02:32:58 |
| User entered 'None (0)' | System | 26 Aug 2020 02:32:58 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:32', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '04eab155-80d2-4222-a42d-07fff36ebeed' | System | 26 Aug 2020 02:32:58 |
| User entered 'None (0)' | System | 26 Aug 2020 02:32:58 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:34', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '04eab155-80d2-4222-a42d-07fff36ebeed' | System | 26 Aug 2020 02:32:58 |
| User entered 'None (0)' | System | 26 Aug 2020 02:32:58 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:36', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '04eab155-80d2-4222-a42d-07fff36ebeed' | System | 26 Aug 2020 02:32:58 |
| User entered 'None (0)' | System | 26 Aug 2020 02:32:58 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:39', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '04eab155-80d2-4222-a42d-07fff36ebeed' | System | 26 Aug 2020 02:32:58 |
| User entered 'None (0)' | System | 26 Aug 2020 02:32:58 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:51', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '04eab155-80d2-4222-a42d-07fff36ebeed' | System | 26 Aug 2020 02:32:58 |
| User entered 'No (N)' | System | 26 Aug 2020 02:32:58 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-25T21:32:53', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '04eab155-80d2-4222-a42d-07fff36ebeed' | System | 26 Aug 2020 02:32:58 |
| User entered '25 Aug 2020 21:32' | System | 26 Aug 2020 02:32:58 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 20:16' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 11:59' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 2' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:50', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a5c8a4c6-0d54-4e2e-85d0-94d7ec195106' | System | 27 Aug 2020 05:07:11 |
| User entered 'None (0)' | System | 27 Aug 2020 05:07:11 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:53', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a5c8a4c6-0d54-4e2e-85d0-94d7ec195106' | System | 27 Aug 2020 05:07:11 |
| User entered 'None (0)' | System | 27 Aug 2020 05:07:11 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:55', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a5c8a4c6-0d54-4e2e-85d0-94d7ec195106' | System | 27 Aug 2020 05:07:11 |
| User entered 'None (0)' | System | 27 Aug 2020 05:07:11 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:06:59', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a5c8a4c6-0d54-4e2e-85d0-94d7ec195106' | System | 27 Aug 2020 05:07:11 |
| User entered 'None (0)' | System | 27 Aug 2020 05:07:11 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:07:01', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a5c8a4c6-0d54-4e2e-85d0-94d7ec195106' | System | 27 Aug 2020 05:07:11 |
| User entered 'None (0)' | System | 27 Aug 2020 05:07:11 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:07:03', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a5c8a4c6-0d54-4e2e-85d0-94d7ec195106' | System | 27 Aug 2020 05:07:11 |
| User entered 'None (0)' | System | 27 Aug 2020 05:07:11 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:07:07', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a5c8a4c6-0d54-4e2e-85d0-94d7ec195106' | System | 27 Aug 2020 05:07:11 |
| User entered 'No (N)' | System | 27 Aug 2020 05:07:11 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-27T00:07:10', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a5c8a4c6-0d54-4e2e-85d0-94d7ec195106' User entered '27 Aug 2020 00:07' | System | 27 Aug 2020 05:07:11 |
| | System | 27 Aug 2020 05:07:11 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 12:00' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 11:59' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 3' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:50', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '30502194-d92a-4482-8f15-26306771e288' | System | 28 Aug 2020 07:01:07 |
| User entered 'None (0)' | System | 28 Aug 2020 07:01:07 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:51', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '30502194-d92a-4482-8f15-26306771e288' | System | 28 Aug 2020 07:01:07 |
| User entered 'None (0)' | System | 28 Aug 2020 07:01:07 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:53', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '30502194-d92a-4482-8f15-26306771e288' | System | 28 Aug 2020 07:01:07 |
| User entered 'None (0)' | System | 28 Aug 2020 07:01:07 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:55', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '30502194-d92a-4482-8f15-26306771e288' | System | 28 Aug 2020 07:01:07 |
| User entered 'None (0)' | System | 28 Aug 2020 07:01:07 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:57', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '30502194-d92a-4482-8f15-26306771e288' | System | 28 Aug 2020 07:01:07 |
| User entered 'None (0)' | System | 28 Aug 2020 07:01:07 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:00:59', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '30502194-d92a-4482-8f15-26306771e288' | System | 28 Aug 2020 07:01:07 |
| User entered 'None (0)' | System | 28 Aug 2020 07:01:07 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:01:02', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '30502194-d92a-4482-8f15-26306771e288' | System | 28 Aug 2020 07:01:07 |
| User entered 'No (N)' | System | 28 Aug 2020 07:01:07 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-28T02:01:04', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '30502194-d92a-4482-8f15-26306771e288' | System | 28 Aug 2020 07:01:07 |
| User entered '28 Aug 2020 02:01' | System | 28 Aug 2020 07:01:07 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 12:00' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Aug 2020 11:59' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 4' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:34', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '5d596d2b-e2f9-4119-8241-eb9a9cdc8733' | System | 29 Aug 2020 05:34:15 |
| User entered 'None (0)' | System | 29 Aug 2020 05:34:15 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:36', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '5d596d2b-e2f9-4119-8241-eb9a9cdc8733' | System | 29 Aug 2020 05:34:15 |
| User entered 'None (0)' | System | 29 Aug 2020 05:34:15 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:39', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '5d596d2b-e2f9-4119-8241-eb9a9cdc8733' | System | 29 Aug 2020 05:34:15 |
| User entered 'None (0)' | System | 29 Aug 2020 05:34:15 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:45', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '5d596d2b-e2f9-4119-8241-eb9a9cdc8733' | System | 29 Aug 2020 05:34:15 |
| User entered 'None (0)' | System | 29 Aug 2020 05:34:15 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:48', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '5d596d2b-e2f9-4119-8241-eb9a9cdc8733' | System | 29 Aug 2020 05:34:15 |
| User entered 'None (0)' | System | 29 Aug 2020 05:34:15 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:51', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '5d596d2b-e2f9-4119-8241-eb9a9cdc8733' | System | 29 Aug 2020 05:34:15 |
| User entered 'None (0)' | System | 29 Aug 2020 05:34:15 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:33:56', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '5d596d2b-e2f9-4119-8241-eb9a9cdc8733' | System | 29 Aug 2020 05:34:15 |
| User entered 'No (N)' | System | 29 Aug 2020 05:34:15 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T00:34:13', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '5d596d2b-e2f9-4119-8241-eb9a9cdc8733' | System | 29 Aug 2020 05:34:15 |
| User entered '29 Aug 2020 00:34' | System | 29 Aug 2020 05:34:15 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Aug 2020 12:00' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Aug 2020 11:59' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 5' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:31:09', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'e0ec0161-e91e-4fcf-b640-3ed33323a537' | System | 30 Aug 2020 03:31:32 |
| User entered 'None (0)' | System | 30 Aug 2020 03:31:32 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:31:10', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'e0ec0161-e91e-4fcf-b640-3ed33323a537' | System | 30 Aug 2020 03:31:32 |
| User entered 'None (0)' | System | 30 Aug 2020 03:31:32 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:31:13', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'e0ec0161-e91e-4fcf-b640-3ed33323a537' | System | 30 Aug 2020 03:31:32 |
| User entered 'None (0)' | System | 30 Aug 2020 03:31:32 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:31:15', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'e0ec0161-e91e-4fcf-b640-3ed33323a537' | System | 30 Aug 2020 03:31:32 |
| User entered 'None (0)' | System | 30 Aug 2020 03:31:32 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:31:17', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'e0ec0161-e91e-4fcf-b640-3ed33323a537' | System | 30 Aug 2020 03:31:32 |
| User entered 'None (0)' | System | 30 Aug 2020 03:31:32 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:31:19', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'e0ec0161-e91e-4fcf-b640-3ed33323a537' | System | 30 Aug 2020 03:31:32 |
| User entered 'None (0)' | System | 30 Aug 2020 03:31:32 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:31:28', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'e0ec0161-e91e-4fcf-b640-3ed33323a537' | System | 30 Aug 2020 03:31:32 |
| User entered 'No (N)' | System | 30 Aug 2020 03:31:32 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-29T22:31:30', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'e0ec0161-e91e-4fcf-b640-3ed33323a537' | System | 30 Aug 2020 03:31:32 |
| User entered '29 Aug 2020 22:31' | System | 30 Aug 2020 03:31:32 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Aug 2020 12:00' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '30 Aug 2020 11:59' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 6' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:30', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd07c20a1-5f48-4877-a067-ce826d759db0' | System | 30 Aug 2020 18:14:48 |
| User entered 'None (0)' | System | 30 Aug 2020 18:14:48 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:33', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd07c20a1-5f48-4877-a067-ce826d759db0' | System | 30 Aug 2020 18:14:48 |
| User entered 'None (0)' | System | 30 Aug 2020 18:14:48 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:34', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd07c20a1-5f48-4877-a067-ce826d759db0' | System | 30 Aug 2020 18:14:48 |
| User entered 'None (0)' | System | 30 Aug 2020 18:14:48 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:35', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd07c20a1-5f48-4877-a067-ce826d759db0' | System | 30 Aug 2020 18:14:48 |
| User entered 'None (0)' | System | 30 Aug 2020 18:14:48 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:37', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd07c20a1-5f48-4877-a067-ce826d759db0' | System | 30 Aug 2020 18:14:48 |
| User entered 'None (0)' | System | 30 Aug 2020 18:14:48 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:39', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd07c20a1-5f48-4877-a067-ce826d759db0' | System | 30 Aug 2020 18:14:48 |
| User entered 'None (0)' | System | 30 Aug 2020 18:14:48 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:44', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd07c20a1-5f48-4877-a067-ce826d759db0' | System | 30 Aug 2020 18:14:48 |
| User entered 'No (N)' | System | 30 Aug 2020 18:14:48 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-30T13:14:46', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd07c20a1-5f48-4877-a067-ce826d759db0' | System | 30 Aug 2020 18:14:48 |
| User entered '30 Aug 2020 13:14' | System | 30 Aug 2020 18:14:48 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '30 Aug 2020 12:00' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 11:59' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 7' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:42:18', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '06207fb0-5d5a-48b4-957c-b19af5519396' | System | 01 Sep 2020 03:42:34 |
| User entered 'None (0)' | System | 01 Sep 2020 03:42:34 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:42:20', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '06207fb0-5d5a-48b4-957c-b19af5519396' | System | 01 Sep 2020 03:42:34 |
| User entered 'None (0)' | System | 01 Sep 2020 03:42:34 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:42:22', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '06207fb0-5d5a-48b4-957c-b19af5519396' | System | 01 Sep 2020 03:42:34 |
| User entered 'None (0)' | System | 01 Sep 2020 03:42:34 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:42:23', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '06207fb0-5d5a-48b4-957c-b19af5519396' | System | 01 Sep 2020 03:42:34 |
| User entered 'None (0)' | System | 01 Sep 2020 03:42:34 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:42:25', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '06207fb0-5d5a-48b4-957c-b19af5519396' | System | 01 Sep 2020 03:42:34 |
| User entered 'None (0)' | System | 01 Sep 2020 03:42:34 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:42:27', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '06207fb0-5d5a-48b4-957c-b19af5519396' | System | 01 Sep 2020 03:42:34 |
| User entered 'None (0)' | System | 01 Sep 2020 03:42:34 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:42:29', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '06207fb0-5d5a-48b4-957c-b19af5519396' | System | 01 Sep 2020 03:42:34 |
| User entered 'No (N)' | System | 01 Sep 2020 03:42:34 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-08-31T22:42:31', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '06207fb0-5d5a-48b4-957c-b19af5519396' | System | 01 Sep 2020 03:42:34 |
| User entered '31 Aug 2020 22:42' | System | 01 Sep 2020 03:42:34 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 12:00' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '01 Sep 2020 11:59' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:47:14 |
| User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System). | System | 30 Sep 2020 18:25:01 |
| User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System). | System | 28 Sep 2020 20:15:20 |
| User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System). | System | 24 Sep 2020 17:50:36 |
| User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System). | System | 24 Sep 2020 15:02:05 |
| User entered 'No (N)' | (b) (4), (b) (6) | 24 Sep 2020 15:02:05 |

US3292320

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:47:14 |
| User entered empty. | (b) (4), (b) (6) | 24 Sep 2020 15:02:05 |

US3292320

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:47:14 |
| User entered empty; reason for change Data Entry Error | Dawn Killian (b) (4) | 30 Sep 2020 18:25:01 |
| User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error | (b) (4) | |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 28 Sep 2020 20:15:20 |
| User entered 'Contact Not Made (CONTACT NOT MADE)' | (b) (4) | |
| | Dawn Killian (b) (4) | 24 Sep 2020 17:50:36 |
| | (b) (4) | |
| | (b) (4), (b) (6) | 24 Sep 2020 15:02:05 |

US3292320

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:47:14 |
| User entered 'CONTACT NOT MADE DUE TO ERROR' reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Sep 2020 20:15:20 |
| User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. | System | 24 Sep 2020 17:50:20 |
| Please review and reconcile.' (Site from System). | | |
| User entered 'Not done' reason for change: Data Entry Error | Dawn Killian (b) (4) | 24 Sep 2020 17:50:20 |
| User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. | (b) (4) | |
| Please review and reconcile.' (Site from System). | System | 24 Sep 2020 15:02:05 |
| User entered empty. | (b) (4), (b) (6) | 24 Sep 2020 15:02:05 |
| | | |

US3292320

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:47:19 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 09 Sep 2020 16:51:02 |

US3292320

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 09 Sep 2020 16:51:02 |

US3292320

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:47:01 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 09 Sep 2020 16:51:12 |

US3292320

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| DataPoint Un-verified. | Antonio Gutierrez (b) (4) | 10 Nov 2020 15:45:08 |
| User entered '09 Sep 2020' reason for change: New Information | Antonio Gutierrez (b) (4) | 10 Nov 2020 15:45:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:47:01 |
| User entered '9 Sep 2020' | Kristy Trevino (b) (4) | 09 Sep 2020 16:51:12 |
| | (b) (4) | |

US3292320

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:47:01 |
| User entered 'Contact Made (CONTACT MADE)' | Kristy Trevino (b) (4) (b) (4) | 09 Sep 2020 16:51:12 |

US3292320

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:47:01 |
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 09 Sep 2020 16:51:12 |

US3292320

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:37:15 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 09 Sep 2020 17:05:42 |

US3292320

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 09 Sep 2020 17:05:42 |

US3292320

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 25 Sep 2020 17:09:09 |

US3292320

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered '15 Sep 2020' | Gerardo Pena (b) (4) (b) (4) | 25 Sep 2020 17:09:09 |

US3292320

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Gerardo Pena (b) (4) (b) (4) | 25 Sep 2020 17:09:09 |

US3292320

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 25 Sep 2020 17:09:09 |

US3292320

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------------|----------------------|
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) [REDACTED] | 22 Sep 2020 20:35:19 |

US3292320

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 22 Sep 2020 20:35:19 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:20:55 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered '22 Sep 2020' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:20:55 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:20:55 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'VISIT2' | System | 22 Sep 2020 21:20:55 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:21:32 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

Were vital signs assessed?

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:21:32 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered '22 Sep 2020' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:21:32 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------|---------------------------------|----------------------|
| User entered '14:17' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:21:32 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 14:17' | System | 22 Sep 2020 21:21:32 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------------|----------------------|
| User entered '36.7' C | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:21:32 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'Oral (Oral)' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:21:32 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:21:32 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|-------------------|---------------------------------|----------------------|
| User entered '79' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:21:32 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 22 Sep 2020 21:21:32 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|-------------------|---------------------------------|----------------------|
| User entered '12' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:21:32 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 22 Sep 2020 21:21:32 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------|---------------------------------|----------------------|
| User entered '134' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:21:32 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 22 Sep 2020 21:21:32 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|-------------------|---------------------------------|----------------------|
| User entered '84' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:21:32 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:25

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 22 Sep 2020 21:21:32 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:22:04 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

Were vital signs assessed?

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:22:04 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered '22 Sep 2020' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:22:04 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------|---------------------------------|----------------------|
| User entered '16:00' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:22:04 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 16:00' | System | 22 Sep 2020 21:22:04 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------------|----------------------|
| User entered '36.1' C | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:22:04 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'Oral (Oral)' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:22:04 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:22:04 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|-------------------|---------------------------------|----------------------|
| User entered '82' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:22:04 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 22 Sep 2020 21:22:04 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|-------------------|---------------------------------|----------------------|
| User entered '12' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:22:04 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 22 Sep 2020 21:22:04 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------|---------------------------------|----------------------|
| User entered '131' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:22:04 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 22 Sep 2020 21:22:04 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|-------------------|---------------------------------|----------------------|
| User entered '96' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:22:04 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:25

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 22 Sep 2020 21:22:04 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:25

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:22:23 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:25

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered '22 Sep 2020' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:22:23 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:25

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------------|----------------------|
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) [REDACTED] | 22 Sep 2020 20:35:38 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:25

If No, reason not given

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 22 Sep 2020 20:35:38 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 22 Sep 2020 20:35:38 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:25

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:25

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered '22 Sep 2020' | Nathan Cortez (b) (4) [REDACTED] | 22 Sep 2020 20:35:38 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:25

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|----------------------|-------------------------------------|----------------------|
| User entered '15:30' | Nathan Cortez (b) (4) [REDACTED] | 22 Sep 2020 20:35:38 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:25

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 15:30' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:25

Which arm was used to give treatment?

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------|----------------------|
| User entered 'Left Arm (LEFT ARM)' | Nathan Cortez (b) (4) | 22 Sep 2020 20:35:38 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:25

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:25

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:25

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:22:40 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:25

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered '22 Sep 2020' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:22:40 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:25

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|----------------------|---------------------------------|----------------------|
| User entered '14:25' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:22:40 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:25

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 14:25' | System | 22 Sep 2020 21:22:40 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:52:25

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered '22 Sep 2020' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:23:09 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:52:25

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:23:09 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:52:25

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:23:09 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:52:25

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|----------------------|---------------------------------|----------------------|
| User entered '14:42' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:23:09 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:52:25

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 14:42' | System | 22 Sep 2020 21:23:09 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:52:25

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:23:09 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:52:25

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------------|----------------------|
| User entered 'No (N)' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:23:09 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:52:25

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:23:09 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:52:25

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Sep 2020 21:23:09 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 22 Sep 2020 21:23:15 |

US3292320

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 22 Sep 2020 21:23:15 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 22 Sep 2020 20:35:38 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:02:42', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6c4d9f84-14df-4ff7-8d31-e7f80faf77a9' | System | 22 Sep 2020 21:02:59 |
| User entered 'Yes (Y)' | System | 22 Sep 2020 21:02:59 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:02:49', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6c4d9f84-14df-4ff7-8d31-e7f80faf77a9' | System | 22 Sep 2020 21:02:59 |
| User entered '97.0' | System | 22 Sep 2020 21:02:59 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:02:52', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6c4d9f84-14df-4ff7-8d31-e7f80faf77a9' | System | 22 Sep 2020 21:02:59 |
| User entered 'No (N)' | System | 22 Sep 2020 21:02:59 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:02:57', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6c4d9f84-14df-4ff7-8d31-e7f80faf77a9' | System | 22 Sep 2020 21:02:59 |
| User entered '22 Sep 2020 16:02' | System | 22 Sep 2020 21:02:59 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 15:50' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 18:20' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 22 Sep 2020 20:35:38 |
| User entered 'Day 1, after vaccination (at home)' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:37:32', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a71973ff-c795-4fa2-afda-c2848d746376' | System | 23 Sep 2020 08:37:49 |
| User entered 'Yes (Y)' | System | 23 Sep 2020 08:37:49 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:37:37', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a71973ff-c795-4fa2-afda-c2848d746376' | System | 23 Sep 2020 08:37:49 |
| User entered '97.4' | System | 23 Sep 2020 08:37:49 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:37:41', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a71973ff-c795-4fa2-afda-c2848d746376' | System | 23 Sep 2020 08:37:49 |
| User entered 'No (N)' | System | 23 Sep 2020 08:37:49 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:37:47', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'a71973ff-c795-4fa2-afda-c2848d746376' | System | 23 Sep 2020 08:37:49 |
| User entered '23 Sep 2020 03:37' | System | 23 Sep 2020 08:37:49 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 19:15' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 11:59' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Sep 2020 20:35:38 |
| User entered 'Day 2' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:25

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:10', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '967cac67-879e-482f-9bc0-e4869243b842' | System | 24 Sep 2020 00:29:25 |
| User entered 'Yes (Y)' | System | 24 Sep 2020 00:29:25 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:25

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:15', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '967cac67-879e-482f-9bc0-e4869243b842' | System | 24 Sep 2020 00:29:25 |
| User entered '97.1' | System | 24 Sep 2020 00:29:25 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:17', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '967cac67-879e-482f-9bc0-e4869243b842' | System | 24 Sep 2020 00:29:25 |
| User entered 'No (N)' | System | 24 Sep 2020 00:29:25 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:20', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '967cac67-879e-482f-9bc0-e4869243b842' | System | 24 Sep 2020 00:29:25 |
| User entered '23 Sep 2020 19:29' | System | 24 Sep 2020 00:29:25 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 12:00' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 11:59' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Sep 2020 20:35:38 |
| User entered 'Day 3' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:25

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:37:42', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '7de28a99-2ad0-4eda-9926-dfda128f28fb' | System | 25 Sep 2020 07:38:06 |
| User entered 'Yes (Y)' | System | 25 Sep 2020 07:38:06 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:25

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:37:46', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '7de28a99-2ad0-4eda-9926-dfda128f28fb' | System | 25 Sep 2020 07:38:06 |
| User entered '98.0' | System | 25 Sep 2020 07:38:06 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:37:55', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '7de28a99-2ad0-4eda-9926-dfda128f28fb' | System | 25 Sep 2020 07:38:06 |
| User entered 'No (N)' | System | 25 Sep 2020 07:38:06 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:01', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '7de28a99-2ad0-4eda-9926-dfda128f28fb' User entered '25 Sep 2020 02:38' | System | 25 Sep 2020 07:38:06 |
| | System | 25 Sep 2020 07:38:06 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 12:00' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Sep 2020 11:59' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Sep 2020 20:35:38 |
| User entered 'Day 4' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:25

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:46:24', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '1a63cb07-5284-4cef-9eb2-e7e9c5408360' | System | 26 Sep 2020 01:46:41 |
| User entered 'Yes (Y)' | System | 26 Sep 2020 01:46:41 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:25

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:46:31', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '1a63cb07-5284-4cef-9eb2-e7e9c5408360' | System | 26 Sep 2020 01:46:41 |
| User entered '98.1' | System | 26 Sep 2020 01:46:41 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:46:35', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '1a63cb07-5284-4cef-9eb2-e7e9c5408360' | System | 26 Sep 2020 01:46:41 |
| User entered 'No (N)' | System | 26 Sep 2020 01:46:41 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:46:39', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '1a63cb07-5284-4cef-9eb2-e7e9c5408360' | System | 26 Sep 2020 01:46:41 |
| User entered '25 Sep 2020 20:46' | System | 26 Sep 2020 01:46:41 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Sep 2020 12:00' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 11:59' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Sep 2020 20:35:38 |
| User entered 'Day 5' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:25

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:10:39', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '73d7dd56-e322-4117-a112-03d1cb45e73e' | System | 27 Sep 2020 04:10:53 |
| User entered 'Yes (Y)' | System | 27 Sep 2020 04:10:53 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:25

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:10:44', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '73d7dd56-e322-4117-a112-03d1cb45e73e' | System | 27 Sep 2020 04:10:53 |
| User entered '98.4' | System | 27 Sep 2020 04:10:53 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:10:47', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '73d7dd56-e322-4117-a112-03d1cb45e73e' | System | 27 Sep 2020 04:10:53 |
| User entered 'No (N)' | System | 27 Sep 2020 04:10:53 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:10:51', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '73d7dd56-e322-4117-a112-03d1cb45e73e' User entered '26 Sep 2020 23:10' | System | 27 Sep 2020 04:10:53 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 12:00' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Sep 2020 11:59' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Sep 2020 20:35:38 |
| User entered 'Day 6' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:25

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:42:53', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd0d7d38a-13c0-407d-8a21-451ffb126144' | System | 28 Sep 2020 05:43:06 |
| User entered 'Yes (Y)' | System | 28 Sep 2020 05:43:06 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:25

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:42:58', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd0d7d38a-13c0-407d-8a21-451ffb126144' | System | 28 Sep 2020 05:43:06 |
| User entered '97.6' | System | 28 Sep 2020 05:43:06 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:01', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd0d7d38a-13c0-407d-8a21-451ffb126144' | System | 28 Sep 2020 05:43:06 |
| User entered 'No (N)' | System | 28 Sep 2020 05:43:06 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:04', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd0d7d38a-13c0-407d-8a21-451ffb126144' | System | 28 Sep 2020 05:43:06 |
| User entered '28 Sep 2020 00:43' | System | 28 Sep 2020 05:43:06 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Sep 2020 12:00' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Sep 2020 11:59' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Sep 2020 20:35:38 |
| User entered 'Day 7' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:25

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:36:59', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '0b0cecec-49f1-4ffa-808e-9ac87c6212e4' | System | 29 Sep 2020 04:37:31 |
| User entered 'Yes (Y)' | System | 29 Sep 2020 04:37:31 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:25

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:12', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '0b0cecec-49f1-4ffa-808e-9ac87c6212e4' | System | 29 Sep 2020 04:37:31 |
| User entered '97.7' | System | 29 Sep 2020 04:37:31 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:19', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '0b0cecec-49f1-4ffa-808e-9ac87c6212e4' | System | 29 Sep 2020 04:37:31 |
| User entered 'No (N)' | System | 29 Sep 2020 04:37:31 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:29', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '0b0cecec-49f1-4ffa-808e-9ac87c6212e4' | System | 29 Sep 2020 04:37:31 |
| User entered '28 Sep 2020 23:37' | System | 29 Sep 2020 04:37:31 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Sep 2020 12:00' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Sep 2020 11:59' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 22 Sep 2020 20:35:38 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:02', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '84a41bbb-36e5-4415-99d0-b916e79ad8ba' | System | 22 Sep 2020 21:03:13 |
| User entered 'None (1)' | System | 22 Sep 2020 21:03:13 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:05', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '84a41bbb-36e5-4415-99d0-b916e79ad8ba' | System | 22 Sep 2020 21:03:13 |
| User entered 'No (N)' | System | 22 Sep 2020 21:03:13 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:07', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '84a41bbb-36e5-4415-99d0-b916e79ad8ba' | System | 22 Sep 2020 21:03:13 |
| User entered 'No (N)' | System | 22 Sep 2020 21:03:13 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:09', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '84a41bbb-36e5-4415-99d0-b916e79ad8ba' User entered 'None (1)' | System | 22 Sep 2020 21:03:13 |
| | System | 22 Sep 2020 21:03:13 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:11', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '84a41bbb-36e5-4415-99d0-b916e79ad8ba' User entered '22 Sep 2020 16:03' | System | 22 Sep 2020 21:03:13 |
| | System | 22 Sep 2020 21:03:13 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 15:50' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 18:20' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 22 Sep 2020 20:35:38 |
| User entered 'Day 1, after vaccination (at home)' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:37:51', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'dce9fc38-0859-4c85-9045-75402d25269a' User entered 'None (1)' | System | 23 Sep 2020 08:38:07 |
| | System | 23 Sep 2020 08:38:07 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:37:54', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'dce9fc38-0859-4c85-9045-75402d25269a' | System | 23 Sep 2020 08:38:07 |
| User entered 'No (N)' | System | 23 Sep 2020 08:38:07 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:37:56', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'dce9fc38-0859-4c85-9045-75402d25269a' | System | 23 Sep 2020 08:38:07 |
| User entered 'No (N)' | System | 23 Sep 2020 08:38:07 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:37:58', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'dce9fc38-0859-4c85-9045-75402d25269a' User entered 'None (1)' | System | 23 Sep 2020 08:38:07 |
| | System | 23 Sep 2020 08:38:07 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:38:02', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'dce9fc38-0859-4c85-9045-75402d25269a' User entered '23 Sep 2020 03:38' | System | 23 Sep 2020 08:38:07 |
| | System | 23 Sep 2020 08:38:07 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 19:15' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 11:59' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Sep 2020 20:35:38 |
| User entered 'Day 2' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:25

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:27', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6b8e143e-bdc6-4050-9260-4d4e51989e06' | System | 24 Sep 2020 00:29:42 |
| User entered 'None (1)' | System | 24 Sep 2020 00:29:42 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:30', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6b8e143e-bdc6-4050-9260-4d4e51989e06' | System | 24 Sep 2020 00:29:42 |
| User entered 'No (N)' | System | 24 Sep 2020 00:29:42 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:34', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6b8e143e-bdc6-4050-9260-4d4e51989e06' | System | 24 Sep 2020 00:29:42 |
| User entered 'No (N)' | System | 24 Sep 2020 00:29:42 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:36', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6b8e143e-bdc6-4050-9260-4d4e51989e06' | System | 24 Sep 2020 00:29:42 |
| User entered 'None (1)' | System | 24 Sep 2020 00:29:42 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:38', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '6b8e143e-bdc6-4050-9260-4d4e51989e06' | System | 24 Sep 2020 00:29:42 |
| User entered '23 Sep 2020 19:29' | System | 24 Sep 2020 00:29:42 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 12:00' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 11:59' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Sep 2020 20:35:38 |
| User entered 'Day 3' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:25

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:05', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'fe3f32fe-ae98-4d8a-a410-ac1a518353ce' | System | 25 Sep 2020 07:38:22 |
| User entered 'None (1)' | System | 25 Sep 2020 07:38:22 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:09', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'fe3f32fe-ae98-4d8a-a410-ac1a518353ce' | System | 25 Sep 2020 07:38:22 |
| User entered 'No (N)' | System | 25 Sep 2020 07:38:22 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:12', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'fe3f32fe-ae98-4d8a-a410-ac1a518353ce' | System | 25 Sep 2020 07:38:22 |
| User entered 'No (N)' | System | 25 Sep 2020 07:38:22 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:16', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'fe3f32fe-ae98-4d8a-a410-ac1a518353ce' | System | 25 Sep 2020 07:38:22 |
| User entered 'None (1)' | System | 25 Sep 2020 07:38:22 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:17', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'fe3f32fe-ae98-4d8a-a410-ac1a518353ce' | System | 25 Sep 2020 07:38:22 |
| User entered '25 Sep 2020 02:38' | System | 25 Sep 2020 07:38:22 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 12:00' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Sep 2020 11:59' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Sep 2020 20:35:38 |
| User entered 'Day 4' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:25

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:46:42', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'df10bfc7-d427-4478-9052-480c7eaaf04c' | System | 26 Sep 2020 01:46:54 |
| User entered 'None (1)' | System | 26 Sep 2020 01:46:54 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:46:46', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'df10bfc7-d427-4478-9052-480c7eaaf04c' | System | 26 Sep 2020 01:46:54 |
| User entered 'No (N)' | System | 26 Sep 2020 01:46:54 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:46:48', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'df10bfc7-d427-4478-9052-480c7eaaf04c' | System | 26 Sep 2020 01:46:54 |
| User entered 'No (N)' | System | 26 Sep 2020 01:46:54 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:46:51', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'df10bfc7-d427-4478-9052-480c7eaaf04c' | System | 26 Sep 2020 01:46:54 |
| User entered 'None (1)' | System | 26 Sep 2020 01:46:54 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:46:53', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'df10bfc7-d427-4478-9052-480c7eaaf04c' | System | 26 Sep 2020 01:46:54 |
| User entered '25 Sep 2020 20:46' | System | 26 Sep 2020 01:46:54 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Sep 2020 12:00' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 11:59' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Sep 2020 20:35:38 |
| User entered 'Day 5' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:10:54', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c649ff59-9baf-43d9-be35-802b33173cba' | System | 27 Sep 2020 04:11:09 |
| User entered 'None (1)' | System | 27 Sep 2020 04:11:09 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:10:57', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c649ff59-9baf-43d9-be35-802b33173cba' | System | 27 Sep 2020 04:11:09 |
| User entered 'No (N)' | System | 27 Sep 2020 04:11:09 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:10:58', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c649ff59-9baf-43d9-be35-802b33173cba' | System | 27 Sep 2020 04:11:09 |
| User entered 'No (N)' | System | 27 Sep 2020 04:11:09 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:10:59', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c649ff59-9baf-43d9-be35-802b33173cba' | System | 27 Sep 2020 04:11:09 |
| User entered 'None (1)' | System | 27 Sep 2020 04:11:09 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:11:07', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c649ff59-9baf-43d9-be35-802b33173cba' | System | 27 Sep 2020 04:11:09 |
| User entered '26 Sep 2020 23:11' | System | 27 Sep 2020 04:11:09 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 12:00' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Sep 2020 11:59' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Sep 2020 20:35:38 |
| User entered 'Day 6' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:25

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:07', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '08ebd9f3-e883-4925-885c-2b711db5a169' | System | 28 Sep 2020 05:43:21 |
| User entered 'None (1)' | System | 28 Sep 2020 05:43:21 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:11', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '08ebd9f3-e883-4925-885c-2b711db5a169' | System | 28 Sep 2020 05:43:21 |
| User entered 'No (N)' | System | 28 Sep 2020 05:43:21 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:13', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '08ebd9f3-e883-4925-885c-2b711db5a169' | System | 28 Sep 2020 05:43:21 |
| User entered 'No (N)' | System | 28 Sep 2020 05:43:21 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:16', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '08ebd9f3-e883-4925-885c-2b711db5a169' | System | 28 Sep 2020 05:43:21 |
| User entered 'None (1)' | System | 28 Sep 2020 05:43:21 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:19', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '08ebd9f3-e883-4925-885c-2b711db5a169' | System | 28 Sep 2020 05:43:21 |
| User entered '28 Sep 2020 00:43' | System | 28 Sep 2020 05:43:21 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Sep 2020 12:00' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Sep 2020 11:59' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Sep 2020 20:35:38 |
| User entered 'Day 7' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:34', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8170e434-7a32-4a06-8d72-40304bcf7b45' | System | 29 Sep 2020 04:37:48 |
| User entered 'None (1)' | System | 29 Sep 2020 04:37:48 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:38', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8170e434-7a32-4a06-8d72-40304bcf7b45' | System | 29 Sep 2020 04:37:48 |
| User entered 'No (N)' | System | 29 Sep 2020 04:37:48 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:41', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8170e434-7a32-4a06-8d72-40304bcf7b45' | System | 29 Sep 2020 04:37:48 |
| User entered 'No (N)' | System | 29 Sep 2020 04:37:48 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:43', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8170e434-7a32-4a06-8d72-40304bcf7b45' | System | 29 Sep 2020 04:37:48 |
| User entered 'None (1)' | System | 29 Sep 2020 04:37:48 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:25

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:45', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8170e434-7a32-4a06-8d72-40304bcf7b45' | System | 29 Sep 2020 04:37:48 |
| User entered '28 Sep 2020 23:37' | System | 29 Sep 2020 04:37:48 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Sep 2020 12:00' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Sep 2020 11:59' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 22 Sep 2020 20:35:38 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:16', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9f48112e-07e7-42d1-afc7-2c18561c3381' User entered 'None (0)' | System | 22 Sep 2020 21:03:31 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:18', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9f48112e-07e7-42d1-afc7-2c18561c3381' | System | 22 Sep 2020 21:03:31 |
| User entered 'None (0)' | System | 22 Sep 2020 21:03:31 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:19', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9f48112e-07e7-42d1-afc7-2c18561c3381' | System | 22 Sep 2020 21:03:31 |
| User entered 'None (0)' | System | 22 Sep 2020 21:03:31 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:21', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9f48112e-07e7-42d1-afc7-2c18561c3381' User entered 'None (0)' | System | 22 Sep 2020 21:03:31 |
| | System | 22 Sep 2020 21:03:31 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:22', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9f48112e-07e7-42d1-afc7-2c18561c3381' | System | 22 Sep 2020 21:03:31 |
| User entered 'None (0)' | System | 22 Sep 2020 21:03:31 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:23', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9f48112e-07e7-42d1-afc7-2c18561c3381' | System | 22 Sep 2020 21:03:31 |
| User entered 'None (0)' | System | 22 Sep 2020 21:03:31 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:26', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9f48112e-07e7-42d1-afc7-2c18561c3381' | System | 22 Sep 2020 21:03:31 |
| User entered 'No (N)' | System | 22 Sep 2020 21:03:31 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-22T16:03:28', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9f48112e-07e7-42d1-afc7-2c18561c3381' User entered '22 Sep 2020 16:03' | System | 22 Sep 2020 21:03:31 |
| | System | 22 Sep 2020 21:03:31 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 15:50' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 18:20' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 22 Sep 2020 20:35:38 |
| User entered 'Day 1, after vaccination (at home)' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:38:06', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9d09c055-7b37-47d9-bd27-1cfd3322fe28' | System | 23 Sep 2020 08:38:24 |
| User entered 'None (0)' | System | 23 Sep 2020 08:38:24 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:38:08', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9d09c055-7b37-47d9-bd27-1cfd3322fe28' | System | 23 Sep 2020 08:38:24 |
| User entered 'None (0)' | System | 23 Sep 2020 08:38:24 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:38:10', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9d09c055-7b37-47d9-bd27-1cfd3322fe28' | System | 23 Sep 2020 08:38:24 |
| User entered 'None (0)' | System | 23 Sep 2020 08:38:24 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:38:11', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9d09c055-7b37-47d9-bd27-1cfd3322fe28' | System | 23 Sep 2020 08:38:24 |
| User entered 'None (0)' | System | 23 Sep 2020 08:38:24 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:38:14', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9d09c055-7b37-47d9-bd27-1cfd3322fe28' | System | 23 Sep 2020 08:38:24 |
| User entered 'None (0)' | System | 23 Sep 2020 08:38:24 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:38:15', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9d09c055-7b37-47d9-bd27-1cfd3322fe28' | System | 23 Sep 2020 08:38:24 |
| User entered 'None (0)' | System | 23 Sep 2020 08:38:24 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:38:19', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9d09c055-7b37-47d9-bd27-1cfd3322fe28' | System | 23 Sep 2020 08:38:24 |
| User entered 'No (N)' | System | 23 Sep 2020 08:38:24 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T03:38:22', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '9d09c055-7b37-47d9-bd27-1cfd3322fe28' | System | 23 Sep 2020 08:38:24 |
| User entered '23 Sep 2020 03:38' | System | 23 Sep 2020 08:38:24 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 19:15' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 11:59' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Sep 2020 20:35:38 |
| User entered 'Day 2' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:43', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'edbf0906-599f-490f-b48e-2f048742a39a' | System | 24 Sep 2020 00:30:15 |
| User entered 'None (0)' | System | 24 Sep 2020 00:30:15 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:44', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'edbf0906-599f-490f-b48e-2f048742a39a' | System | 24 Sep 2020 00:30:15 |
| User entered 'None (0)' | System | 24 Sep 2020 00:30:15 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:46', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'edbf0906-599f-490f-b48e-2f048742a39a' | System | 24 Sep 2020 00:30:15 |
| User entered 'None (0)' | System | 24 Sep 2020 00:30:15 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:49', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'edbf0906-599f-490f-b48e-2f048742a39a' | System | 24 Sep 2020 00:30:15 |
| User entered 'None (0)' | System | 24 Sep 2020 00:30:15 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:51', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'edbf0906-599f-490f-b48e-2f048742a39a' | System | 24 Sep 2020 00:30:15 |
| User entered 'None (0)' | System | 24 Sep 2020 00:30:15 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:29:53', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'edbf0906-599f-490f-b48e-2f048742a39a' | System | 24 Sep 2020 00:30:15 |
| User entered 'None (0)' | System | 24 Sep 2020 00:30:15 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:30:05', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'edbf0906-599f-490f-b48e-2f048742a39a' | System | 24 Sep 2020 00:30:15 |
| User entered 'No (N)' | System | 24 Sep 2020 00:30:15 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-23T19:30:06', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'edbf0906-599f-490f-b48e-2f048742a39a' | System | 24 Sep 2020 00:30:15 |
| User entered '23 Sep 2020 19:30' | System | 24 Sep 2020 00:30:15 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 12:00' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 11:59' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Sep 2020 20:35:38 |
| User entered 'Day 3' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:22', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd4f1efdd-e1d2-4e9c-a55a-24aadebad737' | System | 25 Sep 2020 07:38:41 |
| User entered 'None (0)' | System | 25 Sep 2020 07:38:41 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:23', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd4f1efdd-e1d2-4e9c-a55a-24aadebad737' | System | 25 Sep 2020 07:38:41 |
| User entered 'None (0)' | System | 25 Sep 2020 07:38:41 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:25', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd4f1efdd-e1d2-4e9c-a55a-24aadebad737' | System | 25 Sep 2020 07:38:41 |
| User entered 'None (0)' | System | 25 Sep 2020 07:38:41 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:26', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd4f1efdd-e1d2-4e9c-a55a-24aadebad737' | System | 25 Sep 2020 07:38:41 |
| User entered 'None (0)' | System | 25 Sep 2020 07:38:41 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:29', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd4f1efdd-e1d2-4e9c-a55a-24aadebad737' | System | 25 Sep 2020 07:38:41 |
| User entered 'None (0)' | System | 25 Sep 2020 07:38:41 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:31', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd4f1efdd-e1d2-4e9c-a55a-24aadebad737' | System | 25 Sep 2020 07:38:41 |
| User entered 'None (0)' | System | 25 Sep 2020 07:38:41 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:34', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd4f1efdd-e1d2-4e9c-a55a-24aadebad737' | System | 25 Sep 2020 07:38:41 |
| User entered 'No (N)' | System | 25 Sep 2020 07:38:41 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T02:38:37', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'd4f1efdd-e1d2-4e9c-a55a-24aadebad737' | System | 25 Sep 2020 07:38:41 |
| User entered '25 Sep 2020 02:38' | System | 25 Sep 2020 07:38:41 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 12:00' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Sep 2020 11:59' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Sep 2020 20:35:38 |
| User entered 'Day 4' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:46:58', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '508da5e5-f2e3-4f24-bb59-949283b9b4cb' User entered 'None (0)' | System | 26 Sep 2020 01:47:17 |
| | System | 26 Sep 2020 01:47:17 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:46:59', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '508da5e5-f2e3-4f24-bb59-949283b9b4cb' User entered 'None (0)' | System | 26 Sep 2020 01:47:17 |
| | System | 26 Sep 2020 01:47:17 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:47:02', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '508da5e5-f2e3-4f24-bb59-949283b9b4cb' User entered 'None (0)' | System | 26 Sep 2020 01:47:17 |
| | System | 26 Sep 2020 01:47:17 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:47:04', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '508da5e5-f2e3-4f24-bb59-949283b9b4cb' User entered 'None (0)' | System | 26 Sep 2020 01:47:17 |
| | System | 26 Sep 2020 01:47:17 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:47:07', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '508da5e5-f2e3-4f24-bb59-949283b9b4cb' | System | 26 Sep 2020 01:47:17 |
| User entered 'None (0)' | System | 26 Sep 2020 01:47:17 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:47:09', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '508da5e5-f2e3-4f24-bb59-949283b9b4cb' User entered 'None (0)' | System | 26 Sep 2020 01:47:17 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:47:11', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '508da5e5-f2e3-4f24-bb59-949283b9b4cb' | System | 26 Sep 2020 01:47:17 |
| User entered 'No (N)' | System | 26 Sep 2020 01:47:17 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-25T20:47:13', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '508da5e5-f2e3-4f24-bb59-949283b9b4cb' | System | 26 Sep 2020 01:47:17 |
| User entered '25 Sep 2020 20:47' | System | 26 Sep 2020 01:47:17 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Sep 2020 12:00' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 11:59' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Sep 2020 20:35:38 |
| User entered 'Day 5' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:11:10', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '79c24e52-6eaf-4b4e-a566-784a671f1109' | System | 27 Sep 2020 04:11:26 |
| User entered 'None (0)' | System | 27 Sep 2020 04:11:26 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:11:11', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '79c24e52-6eaf-4b4e-a566-784a671f1109' | System | 27 Sep 2020 04:11:26 |
| User entered 'None (0)' | System | 27 Sep 2020 04:11:26 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:11:13', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '79c24e52-6eaf-4b4e-a566-784a671f1109' | System | 27 Sep 2020 04:11:26 |
| User entered 'None (0)' | System | 27 Sep 2020 04:11:26 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:11:15', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '79c24e52-6eaf-4b4e-a566-784a671f1109' | System | 27 Sep 2020 04:11:26 |
| User entered 'None (0)' | System | 27 Sep 2020 04:11:26 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:11:16', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '79c24e52-6eaf-4b4e-a566-784a671f1109' | System | 27 Sep 2020 04:11:26 |
| User entered 'None (0)' | System | 27 Sep 2020 04:11:26 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:11:19', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '79c24e52-6eaf-4b4e-a566-784a671f1109' | System | 27 Sep 2020 04:11:26 |
| User entered 'None (0)' | System | 27 Sep 2020 04:11:26 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:11:21', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '79c24e52-6eaf-4b4e-a566-784a671f1109' | System | 27 Sep 2020 04:11:26 |
| User entered 'No (N)' | System | 27 Sep 2020 04:11:26 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-26T23:11:23', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '79c24e52-6eaf-4b4e-a566-784a671f1109' | System | 27 Sep 2020 04:11:26 |
| User entered '26 Sep 2020 23:11' | System | 27 Sep 2020 04:11:26 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 12:00' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Sep 2020 11:59' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Sep 2020 20:35:38 |
| User entered 'Day 6' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:24', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8aa8531c-9fdc-4596-b312-0f44da54c0d3' | System | 28 Sep 2020 05:43:43 |
| User entered 'None (0)' | System | 28 Sep 2020 05:43:43 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:26', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8aa8531c-9fdc-4596-b312-0f44da54c0d3' | System | 28 Sep 2020 05:43:43 |
| User entered 'None (0)' | System | 28 Sep 2020 05:43:43 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:28', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8aa8531c-9fdc-4596-b312-0f44da54c0d3' | System | 28 Sep 2020 05:43:43 |
| User entered 'None (0)' | System | 28 Sep 2020 05:43:43 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:30', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8aa8531c-9fdc-4596-b312-0f44da54c0d3' | System | 28 Sep 2020 05:43:43 |
| User entered 'None (0)' | System | 28 Sep 2020 05:43:43 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:31', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8aa8531c-9fdc-4596-b312-0f44da54c0d3' | System | 28 Sep 2020 05:43:43 |
| User entered 'None (0)' | System | 28 Sep 2020 05:43:43 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:33', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8aa8531c-9fdc-4596-b312-0f44da54c0d3' | System | 28 Sep 2020 05:43:43 |
| User entered 'None (0)' | System | 28 Sep 2020 05:43:43 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:36', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8aa8531c-9fdc-4596-b312-0f44da54c0d3' | System | 28 Sep 2020 05:43:43 |
| User entered 'No (N)' | System | 28 Sep 2020 05:43:43 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T00:43:40', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '8aa8531c-9fdc-4596-b312-0f44da54c0d3' | System | 28 Sep 2020 05:43:43 |
| User entered '28 Sep 2020 00:43' | System | 28 Sep 2020 05:43:43 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Sep 2020 12:00' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Sep 2020 11:59' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Sep 2020 20:35:38 |
| User entered 'Day 7' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:48', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'cb305a97-395c-4a33-a666-72b931e20cf0' | System | 29 Sep 2020 04:38:06 |
| User entered 'None (0)' | System | 29 Sep 2020 04:38:06 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:52', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'cb305a97-395c-4a33-a666-72b931e20cf0' | System | 29 Sep 2020 04:38:06 |
| User entered 'None (0)' | System | 29 Sep 2020 04:38:06 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:53', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'cb305a97-395c-4a33-a666-72b931e20cf0' | System | 29 Sep 2020 04:38:06 |
| User entered 'None (0)' | System | 29 Sep 2020 04:38:06 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:55', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'cb305a97-395c-4a33-a666-72b931e20cf0' | System | 29 Sep 2020 04:38:06 |
| User entered 'None (0)' | System | 29 Sep 2020 04:38:06 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:57', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'cb305a97-395c-4a33-a666-72b931e20cf0' | System | 29 Sep 2020 04:38:06 |
| User entered 'None (0)' | System | 29 Sep 2020 04:38:06 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:37:59', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'cb305a97-395c-4a33-a666-72b931e20cf0' | System | 29 Sep 2020 04:38:06 |
| User entered 'None (0)' | System | 29 Sep 2020 04:38:06 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:38:02', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'cb305a97-395c-4a33-a666-72b931e20cf0' | System | 29 Sep 2020 04:38:06 |
| User entered 'No (N)' | System | 29 Sep 2020 04:38:06 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-09-28T23:38:04', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'cb305a97-395c-4a33-a666-72b931e20cf0' | System | 29 Sep 2020 04:38:06 |
| User entered '28 Sep 2020 23:38' | System | 29 Sep 2020 04:38:06 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Sep 2020 12:00' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:25

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Sep 2020 11:59' | System | 22 Sep 2020 20:35:38 |

US3292320

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System). | System | 01 Oct 2020 13:28:34 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 01 Oct 2020 13:28:34 |
| User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System). | System | 01 Oct 2020 13:28:25 |
| User entered 'No (N)' | (b) (4), (b) (6) | 01 Oct 2020 13:28:25 |

US3292320

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| User entered '1 Oct 2020' | (b) (4), (b) (6) | 01 Oct 2020 13:28:25 |

US3292320

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered 'Contact Not Made (CONTACT NOT MADE)' | (b) (4), (b) (6) | 01 Oct 2020 13:28:25 |

US3292320

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User entered '3 attempts made to subject, call went straight to voicemail, voicemail box full unable to lvm.' | (b) (4), (b) (6) | 01 Oct 2020 13:28:25 |

US3292320

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 01 Oct 2020 13:28:40 |
| | | |

US3292320

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 01 Oct 2020 13:28:40 |

US3292320

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 06 Oct 2020 22:22:11 |

US3292320

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User entered '6 Oct 2020' | Kristy Trevino (b) (4) (b) (4) | 06 Oct 2020 22:22:11 |

US3292320

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Kristy Trevino (b) (4) (b) (4) | 06 Oct 2020 22:22:11 |

US3292320

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 06 Oct 2020 22:22:11 |

US3292320

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 06 Oct 2020 22:22:28 |

US3292320

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 06 Oct 2020 22:22:28 |

US3292320

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Oct 2020 15:17:44 |

US3292320

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '14 Oct 2020' | (b) (4), (b) (6) | 14 Oct 2020 15:17:44 |

US3292320

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 14 Oct 2020 15:17:44 |

US3292320

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 14 Oct 2020 15:17:44 |

US3292320

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Oct 2020 15:17:52 |

US3292320

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 14 Oct 2020 15:17:52 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kevin Martinez (b) (4) (b) (4) | 21 Oct 2020 20:53:59 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User entered '21 Oct 2020' | Kevin Martinez (b) (4) (b) (4) | 21 Oct 2020 20:53:59 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Kevin Martinez (b) (4) (b) (4) | 21 Oct 2020 20:53:59 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'VISIT3' | System | 21 Oct 2020 20:53:59 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

Were vital signs assessed?

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kevin Martinez (b) (4) (b) (4) | 21 Oct 2020 20:54:41 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User entered '21 Oct 2020' | Kevin Martinez (b) (4) (b) (4) | 21 Oct 2020 20:54:41 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System). | System | 21 Oct 2020 20:54:51 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System | 21 Oct 2020 20:54:51 |
| User entered '10:50' reason for change: Data Entry Error | Kevin Martinez (b) (4) | 21 Oct 2020 20:54:51 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 21 Oct 2020 20:54:41 |
| User entered empty. | Kevin Martinez (b) (4) | 21 Oct 2020 20:54:41 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Oct 2020 10:50' | System | 21 Oct 2020 20:54:51 |
| User entered empty. | System | 21 Oct 2020 20:54:41 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------|-----------------------------------|----------------------|
| User entered '36.6' C | Kevin Martinez (b) (4) (b) (4) | 21 Oct 2020 20:54:41 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (Oral)' | Kevin Martinez (b) (4) (b) (4) | 21 Oct 2020 20:54:41 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kevin Martinez (b) (4) (b) (4) | 21 Oct 2020 20:54:41 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|-------------------|-----------------------------------|----------------------|
| User entered '90' | Kevin Martinez (b) (4) (b) (4) | 21 Oct 2020 20:54:41 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 21 Oct 2020 20:54:41 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|-------------------|-----------------------------------|----------------------|
| User entered '16' | Kevin Martinez (b) (4) (b) (4) | 21 Oct 2020 20:54:41 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 21 Oct 2020 20:54:41 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------|-----------------------------------|----------------------|
| User entered '151' | Kevin Martinez (b) (4) (b) (4) | 21 Oct 2020 20:54:41 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 21 Oct 2020 20:54:41 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|-------------------|-----------------------------------|----------------------|
| User entered '89' | Kevin Martinez (b) (4) (b) (4) | 21 Oct 2020 20:54:41 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 21 Oct 2020 20:54:41 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:25

Was the physical examination performed?

| Audit | User | Time (GMT) |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kevin Martinez (b) (4) (b) (4) | 21 Oct 2020 20:54:55 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:25

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kevin Martinez (b) (4) (b) (4) | 21 Oct 2020 20:54:55 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:25

Was the sample collected?

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kevin Martinez (b) (4) (b) (4) | 21 Oct 2020 20:55:08 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:25

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User entered '21 Oct 2020' | Kevin Martinez (b) (4) (b) (4) | 21 Oct 2020 20:55:08 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:25

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|----------------------|-----------------------------------|----------------------|
| User entered '11:07' | Kevin Martinez (b) (4) (b) (4) | 21 Oct 2020 20:55:08 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:25

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Oct 2020 11:07' | System | 21 Oct 2020 20:55:08 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kevin Martinez (b) (4) (b) (4) | 21 Oct 2020 20:55:14 |

US3292320

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 21 Oct 2020 20:55:14 |

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 64' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-10-26T09:29:06', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c62edd49-fce5-4683-9981-51895e27e8a2' | System | 26 Oct 2020 14:29:18 |
| User entered 'No (N)' | System | 26 Oct 2020 14:29:18 |

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-10-26T09:29:10', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c62edd49-fce5-4683-9981-51895e27e8a2' | System | 26 Oct 2020 14:29:18 |
| User entered 'No (N)' | System | 26 Oct 2020 14:29:18 |

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-10-26T09:29:15', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'c62edd49-fce5-4683-9981-51895e27e8a2' User entered '26 Oct 2020 09:29:15' | System | 26 Oct 2020 14:29:18 |
| | System | 26 Oct 2020 14:29:18 |

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered '25 Oct 2020 00:01' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered '29 Oct 2020 23:59' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 71' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-11-01T04:15:12', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '5cfd6884-86c4-4f8b-aaf0-f15ff0f050db' | System | 01 Nov 2020 10:15:30 |
| User entered 'No (N)' | System | 01 Nov 2020 10:15:30 |

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-11-01T04:15:18', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '5cfd6884-86c4-4f8b-aaf0-f15ff0f050db' | System | 01 Nov 2020 10:15:30 |
| User entered 'No (N)' | System | 01 Nov 2020 10:15:30 |

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-11-01T04:15:25', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '5cfd6884-86c4-4f8b-aaf0-f15ff0f050db' | System | 01 Nov 2020 10:15:30 |
| User entered '01 Nov 2020 04:15:25' | System | 01 Nov 2020 10:15:30 |

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered '01 Nov 2020 00:01' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered '05 Nov 2020 23:59' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered 'Day 78' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-11-09T10:09:10', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '762078ce-0f2d-4144-84b7-94d8a8f7fc5b' | System | 09 Nov 2020 16:11:48 |
| User entered 'No (N)' | System | 09 Nov 2020 16:11:48 |

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-11-09T10:11:37', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '762078ce-0f2d-4144-84b7-94d8a8f7fc5b' | System | 09 Nov 2020 16:11:48 |
| User entered 'No (N)' | System | 09 Nov 2020 16:11:48 |

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-11-09T10:11:45', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: '762078ce-0f2d-4144-84b7-94d8a8f7fc5b' User entered '09 Nov 2020 10:11:45' | System | 09 Nov 2020 16:11:48 |
| | System | 09 Nov 2020 16:11:48 |

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered '08 Nov 2020 00:01' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 25 Aug 2020 21:40:04 |
| User entered '12 Nov 2020 23:59' | System | 25 Aug 2020 21:40:04 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 61' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '22 Oct 2020 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '26 Oct 2020 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 68' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '29 Oct 2020 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '02 Nov 2020 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 75' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '05 Nov 2020 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '09 Nov 2020 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 82' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '12 Nov 2020 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '16 Nov 2020 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 89' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-11-22T00:20:15', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'cbd4eefd-86be-4ec7-bdb9-f80fb21067b0' | System | 22 Nov 2020 06:20:54 |
| User entered 'No (N)' | System | 22 Nov 2020 06:20:54 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

Have you been exposed to someone with 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 (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-11-22T00:20:25', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'cbd4eefd-86be-4ec7-bdb9-f80fb21067b0' | System | 22 Nov 2020 06:20:54 |
| User entered 'No (N)' | System | 22 Nov 2020 06:20:54 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9EBA2293-5964-4302-ABDB-7D10BED446C7)', Time: '2020-11-22T00:20:49', User OID: 'PatientReportedOutcome (US3292320)', ODM File OID: 'cbd4eefd-86be-4ec7-bdb9-f80fb21067b0' | System | 22 Nov 2020 06:20:54 |
| User entered '22 Nov 2020 00:20:49' | System | 22 Nov 2020 06:20:54 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '19 Nov 2020 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '23 Nov 2020 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '26 Nov 2020 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '30 Nov 2020 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '03 Dec 2020 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '07 Dec 2020 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '10 Dec 2020 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '14 Dec 2020 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '17 Dec 2020 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '21 Dec 2020 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '24 Dec 2020 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '28 Dec 2020 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '31 Dec 2020 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '04 Jan 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '07 Jan 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '11 Jan 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '14 Jan 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '18 Jan 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '21 Jan 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '25 Jan 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '28 Jan 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '01 Feb 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '04 Feb 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '08 Feb 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '11 Feb 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '15 Feb 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '18 Feb 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '22 Feb 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '25 Feb 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '01 Mar 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '04 Mar 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '08 Mar 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '11 Mar 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '15 Mar 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '18 Mar 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '22 Mar 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '25 Mar 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '29 Mar 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '01 Apr 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '05 Apr 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '08 Apr 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '12 Apr 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '15 Apr 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '19 Apr 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '22 Apr 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '26 Apr 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '29 Apr 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '03 May 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '06 May 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '10 May 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '13 May 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '17 May 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '20 May 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '24 May 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '27 May 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '31 May 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '03 Jun 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '07 Jun 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '10 Jun 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '14 Jun 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '17 Jun 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '21 Jun 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '24 Jun 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '28 Jun 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '01 Jul 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '05 Jul 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '08 Jul 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '12 Jul 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '15 Jul 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '19 Jul 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '22 Jul 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '26 Jul 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '29 Jul 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '02 Aug 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '05 Aug 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '09 Aug 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '12 Aug 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '16 Aug 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '19 Aug 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '23 Aug 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '26 Aug 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '30 Aug 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '02 Sep 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '06 Sep 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '09 Sep 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '13 Sep 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '16 Sep 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '20 Sep 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '23 Sep 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '27 Sep 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '30 Sep 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '04 Oct 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '07 Oct 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '11 Oct 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '14 Oct 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '18 Oct 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '21 Oct 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '25 Oct 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '28 Oct 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '01 Nov 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '04 Nov 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '08 Nov 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '11 Nov 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '15 Nov 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '18 Nov 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '22 Nov 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '25 Nov 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '29 Nov 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '02 Dec 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '06 Dec 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '09 Dec 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '13 Dec 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '16 Dec 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '20 Dec 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '23 Dec 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '27 Dec 2021 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '30 Dec 2021 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '03 Jan 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '06 Jan 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '10 Jan 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '13 Jan 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '17 Jan 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '20 Jan 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '24 Jan 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '27 Jan 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '31 Jan 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '03 Feb 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '07 Feb 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '10 Feb 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '14 Feb 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '17 Feb 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '21 Feb 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '24 Feb 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '28 Feb 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '03 Mar 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '07 Mar 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '10 Mar 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '14 Mar 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '17 Mar 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '21 Mar 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '24 Mar 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '28 Mar 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '31 Mar 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '04 Apr 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '07 Apr 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '11 Apr 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '14 Apr 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '18 Apr 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '21 Apr 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '25 Apr 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '28 Apr 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '02 May 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '05 May 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '09 May 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '12 May 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '16 May 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '19 May 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '23 May 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '26 May 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '30 May 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '02 Jun 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '06 Jun 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '09 Jun 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '13 Jun 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '16 Jun 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '20 Jun 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '23 Jun 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '27 Jun 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '30 Jun 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '04 Jul 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '07 Jul 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '11 Jul 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '14 Jul 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '18 Jul 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '21 Jul 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '25 Jul 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '28 Jul 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '01 Aug 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '04 Aug 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '08 Aug 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '11 Aug 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '15 Aug 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '18 Aug 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '22 Aug 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '25 Aug 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '29 Aug 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '01 Sep 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '05 Sep 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '08 Sep 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '12 Sep 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '15 Sep 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '19 Sep 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '22 Sep 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '26 Sep 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '29 Sep 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '03 Oct 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '06 Oct 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '10 Oct 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '13 Oct 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '17 Oct 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '20 Oct 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '24 Oct 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '27 Oct 2022 00:01' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:25

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 17:45:48 |
| Amendment Manager: User entered '31 Oct 2022 23:59' | System | 19 Nov 2020 17:45:48 |

US3292320

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 19 Nov 2020 22:37:58 |

US3292320

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered '17 Nov 2020' | Gerardo Pena (b) (4) (b) (4) | 19 Nov 2020 22:37:58 |

US3292320

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Gerardo Pena (b) (4) (b) (4) | 19 Nov 2020 22:37:58 |

US3292320

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:25

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 19 Nov 2020 22:37:58 |

US3292320

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 19 Nov 2020 22:38:03 |

US3292320

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:25

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 19 Nov 2020 22:38:03 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:52:25

[Date of Contact](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered '17 Nov 2020' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:20:18 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:52:25

[Time of Contact](#)

| Audit | User | Time (GMT) |
|----------------------|-------------------------------------|----------------------|
| User entered '16:04' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:20:18 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:52:25

[Date and Time of Contact \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Nov 2020 16:04' | System | 20 Nov 2020 15:20:18 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:52:25

[Type of Contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User entered 'Safety Call (Safety Call)' | Nathan Cortez (b) (4) | 20 Nov 2020 15:20:18 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:52:25

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 20 Nov 2020 15:20:18 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-------------------------------------|----------------------|
| User entered 'Day 1 (Day 1)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:33:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User entered '15 Nov 2020' | Nathan Cortez (b) (4) | 20 Nov 2020 15:33:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|------------------|-------------------------------------|----------------------|
| User entered '0' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:33:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:33:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Nov 2020 15:33:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:33:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'Mild (Mild)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:33:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:33:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:33:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:33:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:33:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:33:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------|----------------------|
| User entered 'Moderate (Moderate)' | Nathan Cortez (b) (4) | 20 Nov 2020 15:33:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'Mild (Mild)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:33:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:33:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:33:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:33:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:33:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:33:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:33:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:33:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:25

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:33:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-------------------------------------|----------------------|
| User entered 'Day 2 (Day 2)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:16 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered '16 Nov 2020' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:16 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|------------------|-------------------------------------|----------------------|
| User entered '0' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:16 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:16 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Nov 2020 15:35:16 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:16 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'Mild (Mild)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:16 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:16 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:16 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:16 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:16 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:16 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------|----------------------|
| User entered 'Moderate (Moderate)' | Nathan Cortez (b) (4) | 20 Nov 2020 15:35:16 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'Mild (Mild)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:16 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:16 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:16 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:16 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) | 20 Nov 2020 15:35:16 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:16 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:16 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:16 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:52:25

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:16 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-------------------------------------|----------------------|
| User entered 'Day 3 (Day 3)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered '17 Nov 2020' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|------------------|-------------------------------------|----------------------|
| User entered '0' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Nov 2020 15:35:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'Mild (Mild)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------|----------------------|
| User entered 'Moderate (Moderate)' | Nathan Cortez (b) (4) | 20 Nov 2020 15:35:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'Mild (Mild)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) | 20 Nov 2020 15:35:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:52:25

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:35:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-------------------------------------|----------------------|
| User entered 'Day 4 (Day 4)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:42:23 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered '18 Nov 2020' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:42:23 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|------------------|-------------------------------------|----------------------|
| User entered '0' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:42:23 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|-------------------|-------------------------------------|----------------------|
| User entered '98' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:42:23 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '%' | System | 20 Nov 2020 15:42:23 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

[Temperature](#)

| Audit | User | Time (GMT) |
|-----------------------|-------------------------------------|----------------------|
| User entered '36.8' C | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:42:23 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

[Chills](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------|----------------------|
| User entered 'Moderate (Moderate)' | Nathan Cortez (b) (4) | 20 Nov 2020 15:42:23 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

[Cough](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------|----------------------|
| User entered 'Moderate (Moderate)' | Nathan Cortez (b) (4) | 20 Nov 2020 15:42:23 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User entered 'None (None)' | Nathan Cortez (b) (4) | 20 Nov 2020 15:42:23 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'None (None)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:42:23 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

Fatigue

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------|----------------------|
| User entered 'Moderate (Moderate)' | Nathan Cortez (b) (4) | 20 Nov 2020 15:42:23 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User entered 'None (None)' | Nathan Cortez (b) (4) | 20 Nov 2020 15:42:23 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------|----------------------|
| User entered 'Moderate (Moderate)' | Nathan Cortez (b) (4) | 20 Nov 2020 15:42:23 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

[Headache](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------|----------------------|
| User entered 'Moderate (Moderate)' | Nathan Cortez (b) (4) | 20 Nov 2020 15:42:23 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'None (None)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:42:23 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'None (None)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:42:23 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'Mild (Mild)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:42:23 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'None (None)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:42:23 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'None (None)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:42:23 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'None (None)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:42:23 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'None (None)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:42:23 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:52:25

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'Mild (Mild)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 15:42:23 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-------------------------------------|----------------------|
| User entered 'Day 5 (Day 5)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 16:02:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered '19 Nov 2020' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 16:02:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|------------------|-------------------------------------|----------------------|
| User entered '0' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 16:02:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|-------------------|-------------------------------------|----------------------|
| User entered '97' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 16:02:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '%' | System | 20 Nov 2020 16:02:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

[Temperature](#)

| Audit | User | Time (GMT) |
|-----------------------|-------------------------------------|----------------------|
| User entered '37.5' C | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 16:02:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'None (None)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 16:02:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'None (None)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 16:02:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'None (None)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 16:02:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'None (None)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 16:02:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'Mild (Mild)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 16:02:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User entered 'None (None)' | Nathan Cortez (b) (4) | 20 Nov 2020 16:02:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'Mild (Mild)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 16:02:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'Mild (Mild)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 16:02:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'None (None)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 16:02:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'None (None)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 16:02:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User entered 'Mild (Mild)' | Nathan Cortez (b) (4) | 20 Nov 2020 16:02:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'None (None)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 16:02:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'None (None)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 16:02:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'None (None)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 16:02:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'None (None)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 16:02:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:52:25

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered 'None (None)' | Nathan Cortez (b) (4) [REDACTED] | 20 Nov 2020 16:02:38 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---------------------------------|----------------------|
| User entered 'Day 6 (Day 6)' | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 21:47:44 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered '20 Nov 2020' | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 21:47:44 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|------------------|---------------------------------|----------------------|
| User entered '0' | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 21:47:44 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|-------------------|---------------------------------|----------------------|
| User entered '97' | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 21:47:44 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '%' | System | 23 Nov 2020 21:47:44 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

[Temperature](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------------|----------------------|
| User entered '36.8' C | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 21:47:44 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'None (None)' | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 21:47:44 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'None (None)' | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 21:47:44 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'None (None)' | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 21:47:44 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'None (None)' | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 21:47:44 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'Mild (Mild)' | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 21:47:44 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'None (None)' | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 21:47:44 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'Mild (Mild)' | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 21:47:44 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'Mild (Mild)' | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 21:47:44 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'None (None)' | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 21:47:44 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'None (None)' | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 21:47:44 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'Mild (Mild)' | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 21:47:44 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'None (None)' | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 21:47:44 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'None (None)' | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 21:47:44 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'None (None)' | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 21:47:44 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'None (None)' | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 21:47:44 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:52:25

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'None (None)' | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 21:47:44 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---------------------------------|----------------------|
| User entered 'Day 7 (Day 7)' | Gerardo Pena (b) (4) (b) (4) | 24 Nov 2020 17:05:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered '21 Nov 2020' | Gerardo Pena (b) (4) (b) (4) | 24 Nov 2020 17:05:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|------------------|---------------------------------|----------------------|
| User entered '0' | Gerardo Pena (b) (4) (b) (4) | 24 Nov 2020 17:05:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|-------------------|---------------------------------|----------------------|
| User entered '96' | Gerardo Pena (b) (4) (b) (4) | 24 Nov 2020 17:05:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '%' | System | 24 Nov 2020 17:05:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

[Temperature](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------------|----------------------|
| User entered '36.2' C | Gerardo Pena (b) (4) (b) (4) | 24 Nov 2020 17:05:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'None (None)' | Gerardo Pena (b) (4) (b) (4) | 24 Nov 2020 17:05:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'None (None)' | Gerardo Pena (b) (4) (b) (4) | 24 Nov 2020 17:05:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'None (None)' | Gerardo Pena (b) (4) (b) (4) | 24 Nov 2020 17:05:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'None (None)' | Gerardo Pena (b) (4) (b) (4) | 24 Nov 2020 17:05:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'Mild (Mild)' | Gerardo Pena (b) (4) (b) (4) | 24 Nov 2020 17:05:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'None (None)' | Gerardo Pena (b) (4) (b) (4) | 24 Nov 2020 17:05:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'None (None)' | Gerardo Pena (b) (4) (b) (4) | 24 Nov 2020 17:05:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'Mild (Mild)' | Gerardo Pena (b) (4) (b) (4) | 24 Nov 2020 17:05:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'None (None)' | Gerardo Pena (b) (4) (b) (4) | 24 Nov 2020 17:05:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'None (None)' | Gerardo Pena (b) (4) (b) (4) | 24 Nov 2020 17:05:42 |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'Mild (Mild)' | Gerardo Pena (b) (4) (b) (4) | 24 Nov 2020 17:05:42 |

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'None (None)' | Gerardo Pena (b) (4) (b) (4) | 24 Nov 2020 17:05:42 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'None (None)' | Gerardo Pena (b) (4) (b) (4) | 24 Nov 2020 17:05:42 |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'None (None)' | Gerardo Pena (b) (4) (b) (4) | 24 Nov 2020 17:05:42 |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'None (None)' | Gerardo Pena (b) (4) (b) (4) | 24 Nov 2020 17:05:42 |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:52:25

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'None (None)' | Gerardo Pena (b) (4) (b) (4) | 24 Nov 2020 17:05:42 |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

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[Date of Visit](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered '18 Nov 2020' | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:23:14 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:52:25

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 23 Nov 2020 16:23:14 |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:52:25

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'Confirmed' (Site from System). | Nathan Cortez (b) (4) | 23 Nov 2020 16:23:21 |
| User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System). | System | 23 Nov 2020 16:23:14 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 23 Nov 2020 16:23:14 |

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Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

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[Date of Test](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered '18 Nov 2020' | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:23:14 |

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Form: COVID Diagnostic Test

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Type of Test Performed

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' | Nathan Cortez (b) (4) | 23 Nov 2020 16:23:14 |

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Form: COVID Diagnostic Test

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[Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:23:14 |

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Form: COVID Diagnostic Test

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Was this diagnostic test performed at a lab other than the Study Central Lab?

| Audit | User | Time (GMT) |
|-----------------------|-----------------------|----------------------|
| User entered 'No (N)' | Nathan Cortez (b) (4) | 23 Nov 2020 16:23:14 |

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Form: COVID Diagnostic Test

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[Lab/ Institution Test Performed](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:23:14 |

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Form: COVID Diagnostic Test

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[CLIA Certified?](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:23:14 |

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Form: COVID Diagnostic Test

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 23 Nov 2020 16:23:14 |

US3292320

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Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:52:25

Did the subject have Respiratory Rates \geq 30 per Minute?

| Audit | User | Time (GMT) |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:52:25

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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Folder: Covid-19 Assessment 17 Nov 2020

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[End Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[Respiratory Rate](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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Form: Covid-19 Severity Assessment

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Did the subject have Heart Rate \geq 125 beats per minute

| Audit | User | Time (GMT) |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[End Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[Heart Rate](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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Form: Covid-19 Severity Assessment

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Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

| Audit | User | Time (GMT) |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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Folder: Covid-19 Assessment 17 Nov 2020

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[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[End Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[Oxygen Saturation](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

| Audit | User | Time (GMT) |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[End Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[PaO2](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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Did the subject have Respiratory failure?

| Audit | User | Time (GMT) |
|-----------------------|-----------------------|----------------------|
| User entered 'No (N)' | Nathan Cortez (b) (4) | 23 Nov 2020 16:57:52 |

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[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

| Audit | User | Time (GMT) |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[High-Flow Oxygen?](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[End Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[Non-Invasive Ventilation?](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[End Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[Mechanical Ventilation?](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[End Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[ECMO?](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[End Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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Form: Covid-19 Severity Assessment

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[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[End Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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Evidence of Shock Requires
Vasopressors

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[End Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[Acute Renal Dysfunction?](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[Hepatic Dysfunction?](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[Neurologic Dysfunction?](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[Clinical Evidence](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[Date of Assessment](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[Radiographical Evidence](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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[Date of Assessment](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

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Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:52:25

[Admission to an intensive care unit due to SARS-CoV-2](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System). | System | 23 Nov 2020 16:57:57 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 23 Nov 2020 16:57:57 |
| User entered 'No (N)' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 23 Nov 2020 16:57:57 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 23 Nov 2020 16:57:52 |
| User entered empty. | Nathan Cortez (b) (4) | 23 Nov 2020 16:57:52 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:52:25

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

US3292320

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:52:25

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:57:52 |

US3292320

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 10:52:25

[Visit](#)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| User accepted default value 'Day 3 (Day 3)' | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 17:03:23 |

US3292320

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 10:52:25

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------------|----------------------|
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 17:03:23 |

US3292320

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 10:52:25

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered '20 Nov 2020' | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 17:03:23 |

US3292320

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 10:52:25

[Visit](#)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| User accepted default value 'Day 5 (Day 5)' | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 17:03:23 |

US3292320

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 10:52:25

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------------|----------------------|
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 17:03:23 |

US3292320

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 10:52:25

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered '22 Nov 2020' | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 17:03:23 |

US3292320

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 10:52:25

[Visit](#)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| User accepted default value 'Day 7 (Day 7)' | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 17:03:23 |

US3292320

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 10:52:25

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Query 'Data is required. Please complete.' answered with 'Pending' (Site from System). | Nathan Cortez (b) (4) | 23 Nov 2020 17:03:33 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 23 Nov 2020 17:03:23 |
| User entered empty. | Nathan Cortez (b) (4) | 23 Nov 2020 17:03:23 |

US3292320

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 10:52:25

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 17:03:23 |

US3292320

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 10:52:25

[Visit](#)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| User accepted default value 'Day 9 (Day 9)' | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 17:03:23 |

US3292320

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 10:52:25

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Query 'Data is required. Please complete.' answered with 'Pending' (Site from System). | Nathan Cortez (b) (4) | 23 Nov 2020 17:03:37 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 23 Nov 2020 17:03:23 |
| User entered empty. | Nathan Cortez (b) (4) | 23 Nov 2020 17:03:23 |

US3292320

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 10:52:25

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 17:03:23 |

US3292320

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 10:52:25

[Visit](#)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| User accepted default value 'Day 14 (Day 14)' | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 17:03:23 |

US3292320

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 10:52:25

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Query 'Data is required. Please complete.' answered with 'Pending' (Site from System). | Nathan Cortez (b) (4) | 23 Nov 2020 17:03:41 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 23 Nov 2020 17:03:23 |
| User entered empty. | Nathan Cortez (b) (4) | 23 Nov 2020 17:03:23 |

US3292320

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 10:52:25

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 17:03:23 |

US3292320

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 10:52:25

[Visit](#)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| User accepted default value 'Day 21 (Day 21)' | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 17:03:23 |

US3292320

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 10:52:25

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Query 'Data is required. Please complete.' answered with 'Pending' (Site from System). | Nathan Cortez (b) (4) | 23 Nov 2020 17:03:46 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 23 Nov 2020 17:03:23 |
| User entered empty. | Nathan Cortez (b) (4) | 23 Nov 2020 17:03:23 |

US3292320

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 10:52:25

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 17:03:23 |

US3292320

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 10:52:25

[Visit](#)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| User accepted default value 'Day 28 (Day 28)' | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 17:03:23 |

US3292320

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 10:52:25

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Query 'Data is required. Please complete.' answered with 'Pending' (Site from System). | Nathan Cortez (b) (4) | 23 Nov 2020 17:03:49 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 23 Nov 2020 17:03:23 |
| User entered empty. | Nathan Cortez (b) (4) | 23 Nov 2020 17:03:23 |

US3292320

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 10:52:25

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 17:03:23 |

US3292320

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:34:08 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 20 Nov 2020 16:08:05 |

US3292320

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:34:09 |
| User entered '18 Nov 2020' | Nathan Cortez (b) (4) | 20 Nov 2020 16:08:05 |

US3292320

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:34:10 |
| User entered 'Home (Home)' | Nathan Cortez (b) (4) | 20 Nov 2020 16:08:05 |

US3292320

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:25

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'SICKD1' | System | 20 Nov 2020 16:08:05 |

US3292320

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:35:12 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 20 Nov 2020 16:09:03 |

US3292320

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:35:13 |
| User entered '18 Nov 2020' | Nathan Cortez (b) (4) | 20 Nov 2020 16:09:03 |

US3292320

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:35:14 |
| User entered '15:27' | Nathan Cortez (b) (4) | 20 Nov 2020 16:09:03 |

US3292320

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '18 Nov 2020 15:27' | System | 20 Nov 2020 16:09:03 |

US3292320

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Height \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:35:16 |
| User entered '175.3' cm | Nathan Cortez (b) (4) | 20 Nov 2020 16:09:03 |
| DataPoint set to visible. | System | 20 Nov 2020 16:08:05 |

US3292320

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Weight \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:35:17 |
| User entered '92.5' kg | Nathan Cortez (b) (4) | 20 Nov 2020 16:09:03 |
| DataPoint set to visible. | System | 20 Nov 2020 16:08:05 |

US3292320

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:35:19 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 20 Nov 2020 16:09:10 |
| User entered '36.8' C reason for change: Data Entry Error | Nathan Cortez (b) (4) | 20 Nov 2020 16:09:10 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 20 Nov 2020 16:09:03 |
| User entered '36.8' (non-conformant). | Nathan Cortez (b) (4) | 20 Nov 2020 16:09:03 |

US3292320

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:35:20 |
| User entered 'Oral (Oral)' | Nathan Cortez (b) (4) | 20 Nov 2020 16:09:03 |

US3292320

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:35:21 |
| User entered empty. | Nathan Cortez (b) (4) | 20 Nov 2020 16:09:03 |

US3292320

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:35:23 |
| User entered '79' | Nathan Cortez (b) (4) | 20 Nov 2020 16:09:03 |

US3292320

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 20 Nov 2020 16:09:03 |

US3292320

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:35:24 |
| User entered '17' | Nathan Cortez (b) (4) | 20 Nov 2020 16:09:03 |

US3292320

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 20 Nov 2020 16:09:03 |

US3292320

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:35:25 |
| User entered '139' | Nathan Cortez (b) (4) | 20 Nov 2020 16:09:03 |

US3292320

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 20 Nov 2020 16:09:03 |

US3292320

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:35:27 |
| User entered '79' | Nathan Cortez (b) (4) | 20 Nov 2020 16:09:03 |

US3292320

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:25

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 20 Nov 2020 16:09:03 |

US3292320

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:25

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:35:55 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 20 Nov 2020 16:09:18 |

US3292320

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:25

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:35:57 |
| User entered '18 Nov 2020' | Nathan Cortez (b) (4) | 20 Nov 2020 16:09:18 |

US3292320

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 10:52:25

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:36:21 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 20 Nov 2020 16:09:32 |

US3292320

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 10:52:25

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:36:22 |
| User entered '18 Nov 2020' | Nathan Cortez (b) (4) | 20 Nov 2020 16:09:32 |

US3292320

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:52:25

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:36 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Sep 2020 16:10:39 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[AEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:01 |
| User entered 'USA-US072-2020-mRNA-1273-P301000003' | System | 23 Sep 2020 14:38:57 |
| User entered 'New' | (b) (4), (b) (6) | 23 Sep 2020 14:38:57 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Cartilage injury, LLT: Acetabular labral tear - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 12 Nov 2020 21:52:36 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 12 Nov 2020 21:52:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:06:01 |
| User closed query 'Per discharge summary from hospital, subject was also diagnosed with the following: Leukocytosis, Urinary Retention, Foraminal hip stenosis L4/L5, Bilateral Hip Osteoarthritis, Trochanteric Bursitis, Iliotibial Band Syndrome. Please update Adverse Event Log as necessary. ' (Site from CRA). | (b) (4), (b) (6) | 06 Nov 2020 19:05:57 |
| Query 'Per discharge summary from hospital, subject was also diagnosed with the following: Leukocytosis, Urinary Retention, Foraminal hip stenosis L4/L5, Bilateral Hip Osteoarthritis, Trochanteric Bursitis, Iliotibial Band Syndrome. Please update Adverse Event Log as necessary. ' answered with 'Updated' (Site from CRA). | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:24:38 |
| Data point term sent to Coder | System | 04 Nov 2020 23:56:25 |
| DataPoint Un-verified. | Antonio Gutierrez (b) (4) | 04 Nov 2020 23:55:37 |
| Coding entries removed. | Antonio Gutierrez (b) (4) | 04 Nov 2020 23:55:37 |
| User entered 'Left HIP LABRUM TEAR' reason for change: New Information | Antonio Gutierrez (b) (4) | 04 Nov 2020 23:55:37 |
| User opened query 'Per discharge summary from hospital, subject was also diagnosed with the following: Leukocytosis, Urinary Retention, Foraminal hip stenosis L4/L5, Bilateral Hip Osteoarthritis, Trochanteric Bursitis, Iliotibial Band Syndrome. Please update Adverse Event Log as necessary. ' (Site from CRA). | (b) (4), (b) (6) | 23 Oct 2020 18:49:34 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Query 'Per discharge summary from hospital, subject was also diagnosed with the following: Leukocytosis Urinary Retention Foraminal hip stenosis L4/L5 Bilateral Hip Osteoarthritis Trochanteric Bursitis Iliotibial Band Syndrome Please update Adverse Event Log as necessary.' canceled (Site from CRA). | (b) (4), (b) (6) | 23 Oct 2020 18:48:52 |
| User opened query 'Per discharge summary from hospital, subject was also diagnosed with the following: Leukocytosis Urinary Retention Foraminal hip stenosis L4/L5 Bilateral Hip Osteoarthritis Trochanteric Bursitis Iliotibial Band Syndrome | (b) (4), (b) (6) | 23 Oct 2020 18:40:39 |
| Please update Adverse Event Log as necessary.' (Site from CRA). | | |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Cartilage injury, LLT: Cartilage injury - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 29 Sep 2020 14:09:59 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 29 Sep 2020 14:09:59 |
| Data point term sent to Coder | System | 22 Sep 2020 22:59:27 |
| Coding entries removed. | Antonio Gutierrez (b) (4) | 22 Sep 2020 22:58:59 |
| User entered 'RIGHT HIP LABRUM TEAR' reason for change: New Information | Antonio Gutierrez (b) (4) | 22 Sep 2020 22:58:59 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Joint injury, LLT: Hip injury - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 21 Sep 2020 07:49:42 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 21 Sep 2020 07:49:42 |
| Data point term sent to Coder | System | 16 Sep 2020 16:13:32 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Adverse event](#)

| Audit | User | Time (GMT) |
|-------------------------------|------------------|----------------------|
| User entered 'Right hip tear' | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User entered 'No (N)' | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User entered 'No (N)' | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User entered '27 Aug 2020' | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). DataPoint Verified. | (b) (4), (b) (6) | 11 Nov 2020 15:55:38 |
| | (b) (4), (b) (6) | 06 Nov 2020 19:06:37 |
| User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'This is unknown. Patient was to follow up with pain specialists and neurosurgery, but has opted out of any surgical or procedural interventions. No updates noted.' (Site from Safety). | (b) (4), (b) (6) | 06 Nov 2020 13:14:12 |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:26:09 |
| User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | (b) (4), (b) (6) | 14 Oct 2020 20:12:27 |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | (b) (4), (b) (6) | 14 Oct 2020 15:15:45 |
| User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'pending' (Site from Safety). | Victoria Hernandez (b) (4) | 13 Oct 2020 21:07:23 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Oct 2020 20:59:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | (b) (4), (b) (6) | 02 Oct 2020 16:28:22 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Severity](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: New Information | Antonio Gutierrez (b) (4) | 22 Sep 2020 22:58:59 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User entered 'Yes (Y)' reason for change: New Information | Antonio Gutierrez (b) (4) | 22 Sep 2020 22:58:59 |
| User entered 'No (N)' | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Death](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User entered '0' | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User entered '0' | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User entered '1' reason for change: New Information | Antonio Gutierrez (b) (4) | 22 Sep 2020 22:58:59 |
| User entered '0' | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User entered '30 Aug 2020' reason for change: New Information | Antonio Gutierrez (b) (4) | 22 Sep 2020 22:58:59 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| DataPoint Un-verified. | Antonio Gutierrez (b) (4) | 04 Nov 2020 23:07:24 |
| User entered '4 Sep 2020' reason for change: New Information | Antonio Gutierrez (b) (4) | 04 Nov 2020 23:07:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User entered '5 Sep 2020' reason for change: New Information | Antonio Gutierrez (b) (4) | 22 Sep 2020 22:58:59 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User entered 'No (N)' reason for change: New Information | Antonio Gutierrez (b) (4) | 22 Sep 2020 22:58:59 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User entered '0' | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User entered '0' | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User entered '0' | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 16 Sep 2020 16:13:31 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 16 Sep 2020 16:13:31 |
| User entered 'None (NONE)' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:13:31 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 16 Sep 2020 16:13:05 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

None

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System). | | 16 Sep 2020 16:13:31 |
| User entered '0' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:13:31 |
| User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System). | System | 16 Sep 2020 16:13:05 |
| User entered '1' | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| User closed query 'Per CDM: Concomitant medication checked however concomitant medication page is missing. Please review and update.' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 15:38:36 |
| Query 'Per CDM: Concomitant medication checked however concomitant medication page is missing. Please review and update.' answered with 'pending' (Site from DM). | Victoria Hernandez (b) (4) | 13 Oct 2020 21:11:29 |
| User opened query 'Per CDM: Concomitant medication checked however concomitant medication page is missing. Please review and update.' (Site from DM). | (b) (4), (b) (6) | 03 Oct 2020 17:01:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User entered 'I' | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User entered '0' | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). DataPoint Verified. | (b) (4), (b) (6) | 11 Nov 2020 15:55:53 |
| | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4), (b) (6) | 06 Nov 2020 13:14:17 |
| Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'This is unknown. Patient was to follow up with pain specialists and neurosurgery, but has opted out of any surgical or procedural interventions. No updates noted.' (Site from Safety). | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:26:46 |
| User entered 'Unknown (UNKNOWN)' reason for change: New Information | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:26:35 |
| User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4), (b) (6) | 14 Oct 2020 20:12:46 |
| User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4), (b) (6) | 14 Oct 2020 15:15:50 |
| Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'pending' (Site from Safety). | Victoria Hernandez (b) (4) | 13 Oct 2020 21:11:20 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Oct 2020 20:59:11 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Outcome](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4), (b) (6) | 02 Oct 2020 16:28:35 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Oct 2020 20:59:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Narrative](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| 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) | 06 Nov 2020 13:14:21 |
| 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 'Emergency Dept/Clinic Course: Dilaudid 0.5mL x2 IV, Dexamethasone 10mg IV once, Fentanyl 100mcg/2mL IV once. No surgical interventions. Discharged with Cyclobenzaprine HCL tab 10mg tid, Methylprednisolone tab 4mg dosepak for 6 days.' (Site from Safety). | Antonio Gutierrez (b) (4) | 05 Nov 2020 21:13:44 |
| 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) | 05 Nov 2020 14:02:19 |
| User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety). | (b) (4), (b) (6) | 05 Nov 2020 14:02:17 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 05 Nov 2020 14:02:16 |
| User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety). | (b) (4), (b) (6) | 05 Nov 2020 14:02:14 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Narrative](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Summary emailed to provided email address 04NOV2020 @ 17:17 Central Time.' (Site from Safety). | Antonio Gutierrez (b) (4) | 04 Nov 2020 23:17:31 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'MRI Pelvis/Hip: Mild bilateral hip osteoarthritis, small tearing of the superior lateral aspect of the L hip acetabular labrum, fluid inflammation. Secondary to recent trauma, trochanteric bursitis, or proximal IT band syndrome. MRI Lumbar Spine: Moderate/Severe right foraminal stenosis at L4/L5 with no significant spinal canal stenosis, also showed disc bulge in L1-S1.' (Site from Safety). | Antonio Gutierrez (b) (4) | 04 Nov 2020 22:54:57 |
| Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'Baseline lumbar pain, obesity, history of frequent chiropractic manipulations of the R hip' (Site from Safety). | Antonio Gutierrez (b) (4) | 04 Nov 2020 22:25:11 |
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'COVID-19 (In-house) SWAB NASOPHARYNGEAL NASOPHARYNGEAL CAVITY collected August 30, 2020 @ 13:05, Result: NEGATIVE' (Site from Safety). | Antonio Gutierrez (b) (4) | 04 Nov 2020 21:31:50 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Oct 2020 20:59:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:57 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Narrative](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| 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) | 02 Oct 2020 18:19:50 |
| User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety). | (b) (4), (b) (6) | 02 Oct 2020 16:29:27 |
| 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) | 02 Oct 2020 16:29:16 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 02 Oct 2020 16:29:06 |
| User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety). | (b) (4), (b) (6) | 02 Oct 2020 16:28:55 |
| User entered 'Patient reported to clinic on 22SEP2020 for V2. During his visit, he reported to Sub-I and CRC that he was actually admitted to the hospital due to what was later diagnosed as a Right Hip Labrum Tear. Will update this post as more information is collected.' reason for change: New Information | Antonio Gutierrez (b) (4) | 22 Sep 2020 22:58:59 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Sep 2020 22:58:59 |
| User entered '0' | System | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 16 Sep 2020 16:13:05 |

US3292320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 22 Sep 2020 22:58:59 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User coded data point as SOC: Blood and lymphatic system disorders, HLGT: White blood cell disorders, HLT: Leukocytoses NEC, PT: Leukocytosis, LLT: Leukocytosis - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 17:48:23 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 17:48:23 |
| Data point term sent to Coder | System | 05 Nov 2020 17:48:10 |
| User entered 'Leukocytosis' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '30 Aug 2020' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Ongoing?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '4 Sep 2020' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Severity](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User opened query 'Per CDM: SAE Narrative is recorded but 'Is the adverse event serious?' is "NO?". Please review and update accordingly else clarify.' (Site from DM). | (b) (4), (b) (6) | 14 Nov 2020 18:06:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Death](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Not Related (NOT RELATED)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Not Related (NOT RELATED)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'None (NONE)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[None](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '1' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Outcome](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Narrative](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Discovered while patient was hospitalized due to torn labrum. Patient continued to be afebrile. Primary differential believed to be leukocytosis secondary to steroid use.' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 05 Nov 2020 17:47:10 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary retention, LLT: Urinary retention - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 17:52:22 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 17:52:22 |
| Data point term sent to Coder | System | 05 Nov 2020 17:51:14 |
| User entered 'Urinary Retention' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '30 Aug 2020' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Ongoing?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '4 Sep 2020' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Severity](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User opened query 'Per CDM: SAE Narrative is recorded but 'Is the adverse event serious?' is "NO?". Please review and update accordingly else clarify.' (Site from DM). | (b) (4), (b) (6) | 14 Nov 2020 18:07:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Death](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Not Related (NOT RELATED)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Not Related (NOT RELATED)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'None (NONE)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[None](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Per Narrative, a Catheter was placed. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM). DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 23:45:27 |
| | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'I' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Outcome](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Narrative](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Discovered while patient was hospitalized for torn labrum. Catheter was placed, no further intervention required.' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 05 Nov 2020 17:51:13 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Vertebral foraminal stenosis, LLT: Lumbar foraminal stenosis - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 23:13:33 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 23:13:33 |
| Data point term sent to Coder | System | 05 Nov 2020 17:56:20 |
| User entered 'Foraminal Stenosis L4/L5' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '30 Aug 2020' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[Severity](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User opened query 'Per CDM: SAE Narrative is recorded but 'Is the adverse event serious?' is "NO?". Please review and update accordingly else clarify.' (Site from DM). | (b) (4), (b) (6) | 14 Nov 2020 18:07:43 |
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[Death](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Not Related (NOT RELATED)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Not Related (NOT RELATED)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'None (NONE)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[None](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'I' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[Outcome](#)

| Audit | User | Time (GMT) |
|----------------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Unknown (UNKNOWN)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[Narrative](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Discovered while patient was hospitalized for torn labrum. Patient was due to follow up with neurosurgery, but at last visit, patient states he was not moving forward with any surgical intervention.' | Antonio Gutierrez (b) (4) | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 05 Nov 2020 17:55:46 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 18:12:21 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 18:12:21 |
| Data point term sent to Coder | System | 05 Nov 2020 18:11:49 |
| User entered 'Bilateral Hip Osteoarthritis' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '30 Aug 2020' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Severity](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User opened query 'Per CDM: SAE Narrative is recorded but 'Is the adverse event serious?' is "NO?". Please review and update accordingly else clarify.' (Site from DM). | (b) (4), (b) (6) | 14 Nov 2020 18:08:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Death](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Not Related (NOT RELATED)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Not Related (NOT RELATED)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'None (NONE)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[None](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'I' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Outcome](#)

| Audit | User | Time (GMT) |
|----------------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Unknown (UNKNOWN)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Narrative](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| User opened query 'Per DM CLR: SAE Narrative = PT ALREADY HAD A MEDICAL HISTORY OF GENERAL OSTEOARTHRITIS. However, recorded MH is SPINAL OSTEOARTHRITIS. Please review and reconcile data as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 23:45:45 |
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Discovered while patient was hospitalized for torn labrum. No additional interventions noted. Pt already had a medical history of general osteoarthritis.' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:52:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 05 Nov 2020 18:11:06 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Synovial and bursal disorders, HLT: Bursal disorders, PT: Bursitis, LLT: Trochanteric bursitis - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 18:22:25 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 18:22:25 |
| Data point term sent to Coder | System | 05 Nov 2020 18:22:01 |
| User entered 'Trochanteric bursitis' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '30 Aug 2020' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

If not Ongoing, end date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Severity](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User opened query 'Per CDM: SAE Narrative is recorded but 'Is the adverse event serious?' is "NO?". Please review and update accordingly else clarify.' (Site from DM). | (b) (4), (b) (6) | 14 Nov 2020 18:08:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Death](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Not Related (NOT RELATED)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Not Related (NOT RELATED)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'None (NONE)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[None](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'I' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Outcome](#)

| Audit | User | Time (GMT) |
|----------------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Unknown (UNKNOWN)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Narrative](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Discovered while patient was hospitalized for torn labrum. No further intervention noted. Patient was to follow up with pain specialists and neurosurgery, but patient opted out of any surgical interventions.' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 05 Nov 2020 18:21:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Iliotibial band syndrome, LLT: Iliotibial band syndrome - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 18:25:21 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 18:25:21 |
| Data point term sent to Coder | System | 05 Nov 2020 18:24:07 |
| User entered 'Iliotibial Band Syndrome' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '30 Aug 2020' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Severity](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User opened query 'Per CDM: SAE Narrative is recorded but 'Is the adverse event serious?' is "NO?". Please review and update accordingly else clarify.' (Site from DM). | (b) (4), (b) (6) | 14 Nov 2020 18:08:51 |
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'No (N)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Death](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Not Related (NOT RELATED)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'Not Related (NOT RELATED)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'None (NONE)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[None](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'I' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered '0' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Outcome](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 05 Nov 2020 18:24:13 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 05 Nov 2020 18:24:13 |
| User entered 'Unknown (UNKNOWN)' reason for change: Per Query Resolution | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:24:13 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 05 Nov 2020 18:23:33 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Narrative](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:07:35 |
| User entered 'DISCOVERED WHILE PATIENT WAS HOSPITALIZED FOR TORN LABRUM. NO FURTHER INTERVENTION NOTED. PATIENT WAS TO FOLLOW UP WITH PAIN SPECIALISTS AND NEUROSURGERY, BUT PATIENT OPTED OUT OF ANY SURGICAL INTERVENTIONS.' | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:24:13 |
| reason for change: New Information | | |
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 05 Nov 2020 18:23:33 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[AEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:43 |
| User entered 'USA-US072-2020-mRNA-1273-P301000014' | System | 24 Nov 2020 13:54:38 |
| User entered 'New' | (b) (4), (b) (6) | 24 Nov 2020 13:54:38 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 24 Nov 2020 12:07:01 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 24 Nov 2020 12:07:01 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:29:27 |
| Data point term sent to Coder | System | 23 Nov 2020 16:28:21 |
| User entered 'Positive Symptomatic COVID-19' | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:29:31 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:29:33 |
| User entered 'No (N)' | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:29:36 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:29:39 |
| User entered '15 Nov 2020' | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:29:41 |
| User entered empty. | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:29:42 |
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

If not Ongoing, end date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:29:44 |
| User entered empty. | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:29:45 |
| User entered empty. | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Severity](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:29:47 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:29:49 |
| User entered 'No (N)' | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Death](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:30:29 |
| User entered '0' | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:30:30 |
| User entered '0' | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:30:32 |
| User entered '0' | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:30:33 |
| User entered empty. | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:30:35 |
| User entered empty. | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:30:53 |
| User entered empty. | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:30:54 |
| User entered empty. | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:30:56 |
| User entered '0' | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:30:57 |
| User entered '0' | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:31:02 |
| User entered '0' | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety). | (b) (4), (b) (6) | 24 Nov 2020 23:25:01 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 23 Nov 2020 16:27:51 |
| User entered empty. | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| User opened query 'Data is required. Please complete.' (Site from System). | System | 23 Nov 2020 16:27:51 |
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| User opened query 'Data is required. Please complete.' (Site from System). | System | 23 Nov 2020 16:27:51 |
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[None](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:31:10 |
| User entered '1' | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:31:12 |
| User entered '0' | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:31:13 |
| User entered '0' | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| User opened query 'Data is required. Please complete.' (Site from System). | System | 23 Nov 2020 16:27:51 |
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:31:17 |
| User entered empty. | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Narrative](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:31:23 |
| User entered 'SYMPTOMS STARTED 15-NOV, ILLNESS VISIT OCCURED ON 18-NOV. POSITIVE ALERT ON 23-NOV. PATIENT WITH RECENT TRAVEL out of state' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 23 Nov 2020 16:45:14 |
| User entered 'SYMPTOMS STARTED 15-NOV, ILLNESS VISIT OCCURED ON 18-NOV. POSITIVE ALERT ON 23-NOV. Patient with recent travel to Mexico.' reason for change: Data Entry Error | Nathan Cortez (b) (4) | 23 Nov 2020 16:29:17 |
| User entered 'Symptoms started 15-NOV, Illness visit occurred on 18-Nov. Positive alert on 23-Nov.' | Nathan Cortez (b) (4) | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 23 Nov 2020 16:27:51 |

US3292320

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 26 Nov 2020 10:52:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 23 Nov 2020 16:27:51 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| User closed query 'Per hospital discharge summary, subject was prescribed Cyclobenzaprine and Methylprednisolone. Please update Con Med Log.' (Site from CRA). | (b) (4), (b) (6) | 06 Nov 2020 19:11:12 |
| User closed query 'Per ETRTR: Please confirm medication dosed for SAE "Right Hip Labrum Tear", thanks' (Site from CRA). | (b) (4), (b) (6) | 06 Nov 2020 19:11:09 |
| Query 'Per hospital discharge summary, subject was prescribed Cyclobenzaprine and Methylprednisolone. Please update Con Med Log.' answered with 'updated' (Site from CRA). | Dawn Killian (b) (4) | 29 Oct 2020 16:35:28 |
| User opened query 'Per hospital discharge summary, subject was prescribed Cyclobenzaprine and Methylprednisolone. Please update Con Med Log.' (Site from CRA). | (b) (4), (b) (6) | 23 Oct 2020 18:43:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:17 |
| Query 'Per ETRTR: Please confirm medication dosed for SAE "Right Hip Labrum Tear", thanks' answered with 'MEDICATION CONFIRMED IN ESOURCE AND CONMED LOG' (Site from CRA). | Victoria Hernandez (b) (4) | 28 Sep 2020 18:33:23 |
| User opened query 'Per ETRTR: Please confirm medication dosed for SAE "Right Hip Labrum Tear", thanks' (Site from CRA). | (b) (4), (b) (6) | 27 Sep 2020 19:33:21 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 19:33:58 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:25

Name of Medication

| Audit | User | Time (GMT) |
|--|--------------------------------------|--|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 23 Sep 2020 20:33:39 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 23 Sep 2020 20:33:39 |
| Data point term sent to Coder Coding entries removed. | System Victoria Hernandez (b) (4) | 23 Sep 2020 15:46:06 23 Sep 2020 15:45:15 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 27 Aug 2020 19:54:32 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 27 Aug 2020 19:54:32 |
| Data point term sent to Coder User entered 'Aspirin' | System (b) (4), (b) (6) | 27 Aug 2020 19:35:36 27 Aug 2020 19:35:25 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:25

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Victoria Hernandez (b) (4) | 23 Sep 2020 15:44:29 |
| User entered 'No (N)' | (b) (4) | |
| | (b) (4), (b) (6) | 27 Aug 2020 19:35:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:25

[Indication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------------|----------------------|
| User closed query 'Per source, subject has been taking Atorvastatin since 2018. Please update conmed list and also medical history conditions for hypercholesterolemia, if appropriate.' (Site from CRA). | (b) (4), (b) (6) | 06 Nov 2020 19:11:55 |
| Query 'Per source, subject has been taking Atorvastatin since 2018. Please update conmed list and also medical history conditions for hypercholesterolemia, if appropriate.' answered with 'updated' (Site from CRA). | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:30:58 |
| User opened query 'Per source, subject has been taking Atorvastatin since 2018. Please update conmed list and also medical history conditions for hypercholesterolemia, if appropriate.' (Site from CRA). | (b) (4), (b) (6) | 22 Oct 2020 21:03:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match.' answered with 'UPDATED' (Site from DM). | Victoria Hernandez (b) (4) (b) (4) | 23 Sep 2020 15:45:20 |
| User entered 'preventative heart health' reason for change: Data Entry Error | Victoria Hernandez (b) (4) (b) (4) | 23 Sep 2020 15:45:15 |
| User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM). | (b) (4), (b) (6) | 22 Sep 2020 10:55:52 |
| User entered 'blood thinner' | (b) (4), (b) (6) | 27 Aug 2020 19:35:25 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:25

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered '81' | (b) (4), (b) (6) | 27 Aug 2020 19:35:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:25

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 27 Aug 2020 19:35:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:25

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 19:35:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:25

[Frequency](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'other (OTHER)' | (b) (4), (b) (6) | 27 Aug 2020 19:35:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:25

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'BIW' | (b) (4), (b) (6) | 27 Aug 2020 19:35:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:25

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 27 Aug 2020 19:35:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:25

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 19:35:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:25

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'un UNK 2019' | (b) (4), (b) (6) | 27 Aug 2020 19:35:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:25

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 19:35:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:25

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 19:35:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:25

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 19:35:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:25

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 19:35:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:25

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Aug 2020 19:35:25 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:25

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Aug 2020 19:35:25 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:25

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Aug 2020 19:35:25 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:25

Name of Medication

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 23 Nov 2020 08:16:12 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 23 Nov 2020 08:16:12 |
| Data point term sent to Coder | System | 09 Nov 2020 21:47:27 |
| User closed query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug. ' (Site from System). | System | 09 Nov 2020 21:46:53 |
| Query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug. ' answered with 'Updated' (Site from System). | (b) (4), (b) (6) | 09 Nov 2020 21:46:53 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 09 Nov 2020 21:46:43 |
| User entered 'MOTRIN (ibuprofen)' reason for change: Per Query Resolution | (b) (4), (b) (6) | 09 Nov 2020 21:46:43 |
| User opened query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug. ' (Site from System). | Coder Import (b) (4) (b) (4) | 06 Nov 2020 11:04:33 |
| Data point term sent to Coder | System | 29 Oct 2020 16:32:14 |
| Coding entries removed. | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:31:33 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:25

Name of Medication

| Audit | User | Time (GMT) |
|---|---------------------------------------|----------------------|
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 24 Sep 2020 12:13:43 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 24 Sep 2020 12:13:43 |
| Data point term sent to Coder | System | 23 Sep 2020 15:52:29 |
| Data point term sent to Coder | System | 23 Sep 2020 15:47:09 |
| Coding entries removed. | Victoria Hernandez (b) (4) (b) (4) | 23 Sep 2020 15:46:56 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 23 Sep 2020 15:46:42 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 23 Sep 2020 15:46:42 |
| Data point term sent to Coder | System | 23 Sep 2020 15:46:07 |
| Coding entries removed. | Victoria Hernandez (b) (4) (b) (4) | 23 Sep 2020 15:45:56 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 27 Aug 2020 19:54:34 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:25

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User coded data point as Term Coded data point by | Coder Import (b) (4) | 27 Aug 2020 19:54:34 |
| User: Coder System - version | (b) (4) | |
| WHODrug-Global-B3\\202003. | | |
| Data point term sent to Coder | System | 27 Aug 2020 19:36:38 |
| User entered 'motrin' | (b) (4), (b) (6) | 27 Aug 2020 19:35:55 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:25

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 19:35:55 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:25

[Indication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Nov 2020 02:44:30 |
| User closed query 'Source does not specify OA pain. Please considering updating source.' (Site from CRA). | (b) (4), (b) (6) | 16 Nov 2020 02:44:29 |
| Query 'Source does not specify OA pain. Please considering updating source.' answered with 'updated' (Site from CRA). | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:31:39 |
| DataPoint Un-verified. | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:31:33 |
| User entered 'generalized OSTEOARTHRITIS PAIN' reason for change: Data Entry Error | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:31:33 |
| User opened query 'Source does not specify OA pain. Please considering updating source.' (Site from CRA). | (b) (4), (b) (6) | 22 Oct 2020 20:58:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User closed query 'Per DM CLR: Please note that there is no MH that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the MH eCRF if appropriate.' (Site from DM). | (b) (4), (b) (6) | 07 Oct 2020 13:09:12 |
| User closed query 'Per DM CLR: Please update the indication to reflect the location/type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM). | (b) (4), (b) (6) | 07 Oct 2020 13:09:10 |
| User entered 'OSTEOARTHRITIS PAIN' reason for change: Data Entry Error | Victoria Hernandez (b) (4) (b) (4) | 23 Sep 2020 15:52:08 |
| Query 'Per DM CLR: Please note that there is no MH that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the MH eCRF if appropriate.' answered with 'UPDATED' (Site from DM). | Victoria Hernandez (b) (4) (b) (4) | 23 Sep 2020 15:47:01 |
| User entered 'GENERALIZED OSTEOARTHRITIS PAIN' reason for change: Data Entry Error | Victoria Hernandez (b) (4) (b) (4) | 23 Sep 2020 15:46:56 |
| Query 'Per DM CLR: Please update the indication to reflect the location/type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'UPDATED' (Site from DM). | Victoria Hernandez (b) (4) (b) (4) | 23 Sep 2020 15:46:02 |
| User entered 'GENERALIZED PAIN' reason for change: Data Entry Error | Victoria Hernandez (b) (4) (b) (4) | 23 Sep 2020 15:45:56 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:25

[Indication](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User opened query 'Per DM CLR: Please note that there is no MH that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the MH eCRF if appropriate.' (Site from DM). | (b) (4), (b) (6) | 23 Sep 2020 04:02:51 |
| User opened query 'Per DM CLR: Please update the indication to reflect the location/type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 23 Sep 2020 04:00:13 |
| User entered 'pain' | (b) (4), (b) (6) | 27 Aug 2020 19:35:55 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:25

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered '200' | (b) (4), (b) (6) | 27 Aug 2020 19:35:55 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:25

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 27 Aug 2020 19:35:55 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:25

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 19:35:55 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:25

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'as needed (PRN)' | (b) (4), (b) (6) | 27 Aug 2020 19:35:55 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:25

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 19:35:55 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:25

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 27 Aug 2020 19:35:55 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:25

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 19:35:55 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'un UNK 1990' | (b) (4), (b) (6) | 27 Aug 2020 19:35:55 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:25

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 19:35:55 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:25

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 19:35:55 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:25

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 19:35:55 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:25

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 19:35:55 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:25

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Aug 2020 19:35:55 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:25

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Aug 2020 19:35:55 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:25

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Aug 2020 19:35:55 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:25

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 27 Aug 2020 19:54:35 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 27 Aug 2020 19:54:35 |
| Data point term sent to Coder | System | 27 Aug 2020 19:36:39 |
| User entered 'amlodipine' | (b) (4), (b) (6) | 27 Aug 2020 19:36:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:25

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 19:36:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:25

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'hypertension' | (b) (4), (b) (6) | 27 Aug 2020 19:36:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:25

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered '10' | (b) (4), (b) (6) | 27 Aug 2020 19:36:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:25

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 27 Aug 2020 19:36:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:25

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 19:36:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:25

[Frequency](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'twice daily (BID)' reason for change: | Victoria Hernandez (b) (4) | 23 Sep 2020 15:47:25 |
| Data Entry Error | (b) (4) | |
| User entered 'other (OTHER)' | (b) (4), (b) (6) | 27 Aug 2020 19:36:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:25

If frequency is Other, specify

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM). | (b) (4), (b) (6) | 07 Oct 2020 13:09:56 |
| Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' answered with 'UPDATED' (Site from DM). | Victoria Hernandez (b) (4) | 23 Sep 2020 15:47:35 |
| User entered empty; reason for change Data Entry Error | (b) (4) | 23 Sep 2020 15:47:25 |
| User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM). | (b) (4), (b) (6) | 22 Sep 2020 10:55:12 |
| User entered 'BIW' | (b) (4), (b) (6) | 27 Aug 2020 19:36:25 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:25

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 27 Aug 2020 19:36:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:25

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 19:36:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:25

Start date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'un UNK 2018' | (b) (4), (b) (6) | 27 Aug 2020 19:36:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:25

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 19:36:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:25

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 19:36:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:25

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 19:36:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:25

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 19:36:25 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:25

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2' | System | 23 Sep 2020 15:47:25 |
| User entered empty. | System | 27 Aug 2020 19:36:25 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:25

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1' | System | 23 Sep 2020 15:47:25 |
| User entered empty. | System | 27 Aug 2020 19:36:25 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:25

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 23 Sep 2020 15:47:25 |
| User entered empty. | System | 27 Aug 2020 19:36:25 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:25

Name of Medication

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 04 Nov 2020 00:55:37 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 04 Nov 2020 00:55:37 |
| Data point term sent to Coder | System | 29 Oct 2020 16:44:40 |
| Data point term sent to Coder | System | 29 Oct 2020 16:34:18 |
| Coding entries removed. | Dawn Killian (b) (4) | 29 Oct 2020 16:33:57 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 23 Sep 2020 23:04:40 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 23 Sep 2020 23:04:40 |
| Data point term sent to Coder | System | 23 Sep 2020 15:51:25 |
| Coding entries removed. | Victoria Hernandez (b) (4) | 23 Sep 2020 15:50:26 |
| | (b) (4) | |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 27 Aug 2020 19:54:41 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 27 Aug 2020 19:54:41 |
| Data point term sent to Coder | System | 27 Aug 2020 19:37:48 |
| User entered 'gabapentin' | (b) (4), (b) (6) | 27 Aug 2020 19:37:03 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:25

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 19:37:03 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:25

[Indication](#)

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| User closed query 'Please update source to include "spinal OA" under condition.' (Site from CRA). | (b) (4), (b) (6) | 16 Nov 2020 02:44:49 |
| User entered 'spinal OSTEOARTHRITIS' reason for change: Data Entry Error | Dawn Killian (b) (4) | 29 Oct 2020 16:43:44 |
| Query 'Please update source to include "spinal OA" under condition.' answered with 'updated' (Site from CRA). | (b) (4) | |
| DataPoint Un-verified. | Dawn Killian (b) (4) | 29 Oct 2020 16:34:06 |
| | (b) (4) | |
| User entered 'generalized OSTEOARTHRITIS' reason for change: Data Entry Error | Dawn Killian (b) (4) | 29 Oct 2020 16:33:57 |
| User opened query 'Please update source to include "spinal OA" under condition.' (Site from CRA). | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:59:19 |
| | (b) (4), (b) (6) | |
| User closed query 'Per DM CLR: Please update the indication and provide the location and laterality of the OSTEOARTHRITIS (e.g. knee; bilateral, left, right). Review and update indication and ensure to update MH eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| Query 'Per DM CLR: Please update the indication and provide the location and laterality of the OSTEOARTHRITIS (e.g. knee; bilateral, left, right). Review and update indication and ensure to update MH eCRF as appropriate. ' answered with 'UPDATED' (Site from DM). | (b) (4), (b) (6) | |
| User entered 'SPINE OSTEOARTHRITIS' reason for change: Data Entry Error | (b) (4), (b) (6) | 07 Oct 2020 13:10:28 |
| User opened query 'Per DM CLR: Please update the indication and provide the location and laterality of the OSTEOARTHRITIS (e.g. knee; bilateral, left, right). Review and update indication and ensure to update MH eCRF as appropriate. ' (Site from DM). | Victoria Hernandez (b) (4) | 23 Sep 2020 15:50:40 |
| User entered 'osteoarthritis' | (b) (4) | |
| | (b) (4) | |
| | (b) (4), (b) (6) | 23 Sep 2020 15:50:26 |
| | (b) (4), (b) (6) | |
| | (b) (4), (b) (6) | 22 Sep 2020 12:13:37 |
| | (b) (4), (b) (6) | |
| | (b) (4), (b) (6) | 27 Aug 2020 19:37:03 |
| | (b) (4), (b) (6) | |
| | (b) (4), (b) (6) | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:25

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered '500' | (b) (4), (b) (6) | 27 Aug 2020 19:37:03 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:25

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 27 Aug 2020 19:37:03 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:25

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 19:37:03 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:25

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'as needed (PRN)' | (b) (4), (b) (6) | 27 Aug 2020 19:37:03 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:25

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 19:37:03 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:25

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 27 Aug 2020 19:37:03 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:25

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 19:37:03 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'un UNK 2008' | (b) (4), (b) (6) | 27 Aug 2020 19:37:03 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:25

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 19:37:03 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:25

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 19:37:03 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:25

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 19:37:03 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:25

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Oct 2020 20:57:44 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 19:37:03 |
| | | |
| | | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:25

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Aug 2020 19:37:03 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:25

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Aug 2020 19:37:03 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:25

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Aug 2020 19:37:03 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:52:25

Name of Medication

| Audit | User | Time (GMT) |
|---|--|----------------------|
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 22:08:28 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 22:08:28 |
| Data point term sent to Coder | System | 05 Nov 2020 22:07:20 |
| DataPoint activated with code reason code Data required. | Antonio Gutierrez (b) (4) (b) (4) | 05 Nov 2020 22:07:15 |
| Data point term sent to Coder | System | 31 Aug 2020 19:50:19 |
| DataPoint inactivated with code reason code Data not required. | Dawn Killian (b) (4) (b) (4) | 31 Aug 2020 19:49:32 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 30 Aug 2020 11:56:32 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 30 Aug 2020 11:56:32 |
| Data point term sent to Coder | System | 27 Aug 2020 19:38:51 |
| User entered 'testosterone treatment' | (b) (4), (b) (6) (b) (4) (b) (4) | 27 Aug 2020 19:37:51 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:52:25

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint activated with code reason code Data required. | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:07:15 |
| DataPoint inactivated with code reason code Data not required. | Dawn Killian (b) (4) | 31 Aug 2020 19:49:32 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 19:37:51 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:52:25

[Indication](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint activated with code reason code Data required. | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:07:15 |
| DataPoint inactivated with code reason code Data not required. | Dawn Killian (b) (4) | 31 Aug 2020 19:49:32 |
| User entered 'low testosterone' | (b) (4), (b) (6) | 27 Aug 2020 19:37:51 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:52:25

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 09 Nov 2020 16:24:57 |
| DataPoint activated with code reason code Data required. | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:07:15 |
| DataPoint inactivated with code reason code Data not required. | Dawn Killian (b) (4) | 31 Aug 2020 19:49:32 |
| Query 'Data is required. Please complete.' answered with 'unknown' (Site from System). | (b) (4), (b) (6) | 27 Aug 2020 19:37:57 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 27 Aug 2020 19:37:51 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 19:37:51 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:52:25

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 09 Nov 2020 16:24:59 |
| DataPoint activated with code reason code Data required. | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:07:15 |
| DataPoint inactivated with code reason code Data not required. | Dawn Killian (b) (4) | 31 Aug 2020 19:49:32 |
| Query 'Data is required. Please complete.' answered with 'unknown' (Site from System). | (b) (4), (b) (6) | 27 Aug 2020 19:38:02 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 27 Aug 2020 19:37:51 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 19:37:51 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:52:25

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint activated with code reason code Data required. | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:07:15 |
| DataPoint inactivated with code reason code Data not required. | Dawn Killian (b) (4) | 31 Aug 2020 19:49:32 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 19:37:51 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:52:25

[Frequency](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint activated with code reason code Data required. | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:07:15 |
| DataPoint inactivated with code reason code Data not required. | Dawn Killian (b) (4) | 31 Aug 2020 19:49:32 |
| User entered 'every week (QS)' | (b) (4), (b) (6) | 27 Aug 2020 19:37:51 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:52:25

If frequency is Other, specify

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint activated with code reason code Data required. | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:07:15 |
| DataPoint inactivated with code reason code Data not required. | Dawn Killian (b) (4) | 31 Aug 2020 19:49:32 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 19:37:51 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:52:25

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 09 Nov 2020 16:25:02 |
| DataPoint activated with code reason code Data required. | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:07:15 |
| DataPoint inactivated with code reason code Data not required. | Dawn Killian (b) (4) | 31 Aug 2020 19:49:32 |
| Query 'Data is required. Please complete.' answered with 'unknown' (Site from System). | (b) (4), (b) (6) | 27 Aug 2020 19:38:05 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 27 Aug 2020 19:37:51 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 19:37:51 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:52:25

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint activated with code reason code Data required. | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:07:15 |
| DataPoint inactivated with code reason code Data not required. | Dawn Killian (b) (4) | 31 Aug 2020 19:49:32 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 19:37:51 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:52:25

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint activated with code reason code Data required. | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:07:15 |
| DataPoint inactivated with code reason code Data not required. | Dawn Killian (b) (4) | 31 Aug 2020 19:49:32 |
| User entered 'un UNK 2008' | (b) (4), (b) (6) | 27 Aug 2020 19:37:51 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:52:25

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint activated with code reason code Data required. | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:07:15 |
| DataPoint inactivated with code reason code Data not required. | Dawn Killian (b) (4) | 31 Aug 2020 19:49:32 |
| User entered '0' | (b) (4), (b) (6) | 27 Aug 2020 19:37:51 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:52:25

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint activated with code reason code Data required. | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:07:15 |
| DataPoint inactivated with code reason code Data not required. | Dawn Killian (b) (4) | 31 Aug 2020 19:49:32 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Aug 2020 19:37:51 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:52:25

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint activated with code reason code Data required. | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:07:15 |
| DataPoint inactivated with code reason code Data not required. | Dawn Killian (b) (4) | 31 Aug 2020 19:49:32 |
| User entered empty. | (b) (4), (b) (6) | 27 Aug 2020 19:37:51 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:52:25

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint activated with code reason code Data required. | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:07:15 |
| DataPoint inactivated with code reason code Data not required. | Dawn Killian (b) (4) | 31 Aug 2020 19:49:32 |
| User entered 'No (N)' | (b) (4), (b) (6) | 27 Aug 2020 19:37:51 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:52:25

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint activated with code reason code Data required. | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:07:15 |
| DataPoint inactivated with code reason code Data not required. | Dawn Killian (b) (4) | 31 Aug 2020 19:49:32 |
| User entered 'I' | System | 27 Aug 2020 19:37:51 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:52:25

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint activated with code reason code Data required. | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:07:15 |
| DataPoint inactivated with code reason code Data not required. | Dawn Killian (b) (4) | 31 Aug 2020 19:49:32 |
| User entered 'I' | System | 27 Aug 2020 19:37:51 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:52:25

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint activated with code reason code Data required. | Antonio Gutierrez (b) (4) | 05 Nov 2020 22:07:15 |
| DataPoint inactivated with code reason code Data not required. | Dawn Killian (b) (4) | 31 Aug 2020 19:49:32 |
| User entered '803 (803)' | System | 27 Aug 2020 19:37:51 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:52:25

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 29 Oct 2020 16:32:19 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 29 Oct 2020 16:32:19 |
| Data point term sent to Coder | System | 29 Oct 2020 16:31:10 |
| User entered 'atorvastatin' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:30:44 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:52:25

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------------|----------------------|
| User entered 'No (N)' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:30:44 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:52:25

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------------|---------------------------------|----------------------|
| User entered 'hypercholesterolemia' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:30:44 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:52:25

[Dose per administration](#)

| Audit | User | Time (GMT) |
|-------------------|---------------------------------|----------------------|
| User entered '30' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:30:44 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:52:25

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'mg (mg)' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:30:44 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:52:25

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:30:44 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:52:25

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| User entered 'once daily (QD)' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:30:44 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:52:25

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:30:44 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:52:25

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:30:44 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:52:25

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:30:44 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:52:25

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'UN UNK 2018' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:30:44 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:52:25

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|---------------------------------|----------------------|
| User entered '0' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:30:44 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:52:25

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:30:44 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:52:25

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:30:44 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:52:25

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------------|----------------------|
| User entered 'No (N)' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:30:44 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:52:25

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 29 Oct 2020 16:30:44 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:52:25

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 29 Oct 2020 16:30:44 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:52:25

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 29 Oct 2020 16:30:44 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:52:25

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 06 Nov 2020 10:56:32 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 06 Nov 2020 10:56:32 |
| Data point term sent to Coder | System | 05 Nov 2020 00:01:27 |
| Coding entries removed. | Antonio Gutierrez (b) (4) | 05 Nov 2020 00:01:02 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 30 Oct 2020 16:27:54 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 30 Oct 2020 16:27:54 |
| Data point term sent to Coder | System | 29 Oct 2020 16:38:25 |
| User entered 'methylprednisolone' | Dawn Killian (b) (4) | 29 Oct 2020 16:37:32 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:52:25

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------------|----------------------|
| User entered 'No (N)' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:37:32 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:52:25

[Indication](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| User entered 'TEAR IN Left HIP LABRUIM' | Antonio Gutierrez (b) (4) | 05 Nov 2020 00:01:02 |
| reason for change: New Information | | |
| User entered 'tear in right hip labruim' | Dawn Killian (b) (4) | 29 Oct 2020 16:37:32 |
| | (b) (4) | |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:52:25

[Dose per administration](#)

| Audit | User | Time (GMT) |
|------------------|---------------------------------|----------------------|
| User entered '4' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:37:32 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:52:25

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'mg (mg)' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:37:32 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:52:25

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:37:32 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:52:25

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| User entered 'once daily (QD)' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:37:32 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:52:25

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:37:32 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:52:25

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:37:32 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:52:25

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:37:32 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:52:25

Start date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered '05 Sep 2020' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:37:32 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:52:25

Start date completely unknown

| Audit | User | Time (GMT) |
|------------------|---------------------------------|----------------------|
| User entered '0' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:37:32 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:52:25

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:37:32 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:52:25

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:37:32 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:52:25

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------------|----------------------|
| User entered 'No (N)' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:37:32 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:52:25

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 29 Oct 2020 16:37:32 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:52:25

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 29 Oct 2020 16:37:32 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:52:25

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 29 Oct 2020 16:37:32 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:52:25

Name of Medication

| Audit | User | Time (GMT) |
|---|--------------------------------------|----------------------|
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 22:27:28 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 22:27:28 |
| Data point term sent to Coder | System | 05 Nov 2020 00:01:27 |
| Coding entries removed. | Antonio Gutierrez (b) (4) (b) (4) | 05 Nov 2020 00:01:20 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 29 Oct 2020 22:10:52 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 29 Oct 2020 22:10:52 |
| Data point term sent to Coder | System | 29 Oct 2020 16:39:28 |
| User entered 'FLEXeril' reason for change: Data Entry Error | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:38:49 |
| User entered 'flexoril' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:38:34 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:52:25

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------------|----------------------|
| User entered 'No (N)' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:38:34 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:52:25

[Indication](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User entered 'TEAR IN Left HIP LABRIUM' reason for change: New Information | Antonio Gutierrez (b) (4) | 05 Nov 2020 00:01:20 |
| User entered 'tear in right hip labrium' | Dawn Killian (b) (4) | 29 Oct 2020 16:38:34 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:52:25

[Dose per administration](#)

| Audit | User | Time (GMT) |
|-------------------|---------------------------------|----------------------|
| User entered '10' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:38:34 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:52:25

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'mg (mg)' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:38:34 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:52:25

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:38:34 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:52:25

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| User entered 'as needed (PRN)' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:38:34 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:52:25

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:38:34 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:52:25

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:38:34 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:52:25

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:38:34 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:52:25

Start date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered '05 Sep 2020' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:38:34 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:52:25

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|---------------------------------|----------------------|
| User entered '0' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:38:34 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:52:25

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:38:34 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:52:25

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:38:34 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:52:25

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------------|----------------------|
| User entered 'No (N)' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:38:34 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:52:25

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Oct 2020 16:38:34 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:52:25

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Oct 2020 16:38:34 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:52:25

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Oct 2020 16:38:34 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:52:25

Name of Medication

| Audit | User | Time (GMT) |
|---|---|--|
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 13:46:17 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 05 Nov 2020 13:46:17 |
| Data point term sent to Coder Coding entries removed. | System Antonio Gutierrez (b) (4) | 05 Nov 2020 00:02:28 05 Nov 2020 00:01:38 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 29 Oct 2020 21:43:44 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 29 Oct 2020 21:43:44 |
| Data point term sent to Coder User entered 'cyclobenzaprine' | System Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:40:30 29 Oct 2020 16:39:55 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:52:25

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------------|----------------------|
| User entered 'No (N)' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:39:55 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:52:25

[Indication](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User entered 'TEAR IN Left HIP LABRUM' reason for change: New Information | Antonio Gutierrez (b) (4) | 05 Nov 2020 00:01:38 |
| User entered 'tear in right hip labrum' | Dawn Killian (b) (4) | 29 Oct 2020 16:39:55 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:52:25

[Dose per administration](#)

| Audit | User | Time (GMT) |
|-------------------|---------------------------------|----------------------|
| User entered '10' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:39:55 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:52:25

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'mg (mg)' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:39:55 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:52:25

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:39:55 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:52:25

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| User entered 'as needed (PRN)' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:39:55 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:52:25

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:39:55 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:52:25

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:39:55 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:52:25

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:39:55 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:52:25

Start date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered '05 Sep 2020' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:39:55 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:52:25

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|---------------------------------|----------------------|
| User entered '0' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:39:55 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:52:25

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:39:55 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:52:25

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:39:55 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:52:25

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------------|----------------------|
| User entered 'No (N)' | Dawn Killian (b) (4) (b) (4) | 29 Oct 2020 16:39:55 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:52:25

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Oct 2020 16:39:55 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:52:25

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Oct 2020 16:39:55 |

US3292320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:52:25

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Oct 2020 16:39:55 |

US3292320

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:52:25

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 00:02:06 |

US3292320

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:52:25

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| User entered '2 Sep 2020' | Antonio Gutierrez (b) (4) | 05 Nov 2020 00:03:54 |

US3292320

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:52:25

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|---------------------------------------|---------------------------|----------------------|
| User entered 'Lumbar/Hip MRI W & W/O' | Antonio Gutierrez (b) (4) | 05 Nov 2020 00:03:54 |

US3292320

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:52:25

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|---------------------------|----------------------|
| User entered 'Adverse Event (AE)' | Antonio Gutierrez (b) (4) | 05 Nov 2020 00:03:54 |

US3292320

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:52:25

If indication is Other, specify

| Audit | User | Time (GMT) |
|---------------------|---------------------------|----------------------|
| User entered empty. | Antonio Gutierrez (b) (4) | 05 Nov 2020 00:03:54 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'USA-US072-2020-MRNA-1273-P301000003' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

Serious

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'Yes (Y)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Death](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'No (N)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Life threatening](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'No (N)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'Yes (Y)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'No (N)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'No (N)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Other medically important event](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'No (N)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'Douglas' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'Denham' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered '7940 Floyd Curl Drive' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'San Antonio' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

Site Address: State

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:01:20 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Nov 2020 14:02:27 |
| Un-reviewed for Safety. | System | 14 Oct 2020 15:16:12 |
| User entered empty. | System | 14 Oct 2020 15:16:12 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 15:16:05 |
| User entered 'Texas' | Victoria Hernandez (b) (4) | 13 Oct 2020 20:46:47 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered '78229' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Investigator Country](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 15:16:05 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| | | |
| User entered 'US' | System | 23 Sep 2020 14:39:25 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 06 Nov 2020 13:14:38 |
| User entered '3' | System | 05 Nov 2020 14:02:37 |
| User entered '2' | System | 14 Oct 2020 15:16:12 |
| User entered '1' | System | 23 Sep 2020 14:39:25 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'USA-US072-2020-MRNA-1273-P301000003' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

Serious

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'Yes (Y)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Death](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'No (N)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Life threatening](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'No (N)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'Yes (Y)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'No (N)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'No (N)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Other medically important event](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'No (N)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'Douglas' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'Denham' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered '7940 Floyd Curl Drive' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'San Antonio' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

Site Address: [State](#)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:01:20 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Nov 2020 14:02:27 |
| Un-reviewed for Safety. | System | 14 Oct 2020 15:16:12 |
| User entered empty. | System | 14 Oct 2020 15:16:12 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 15:16:05 |
| User entered 'Texas' | Victoria Hernandez (b) (4) | 13 Oct 2020 20:46:47 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered '78229' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Investigator Country](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 15:16:05 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| | | |
| User entered 'US' | System | 23 Sep 2020 14:39:25 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 06 Nov 2020 13:14:38 |
| User entered '3' | System | 05 Nov 2020 14:02:37 |
| User entered '2' | System | 14 Oct 2020 15:16:12 |
| User entered '1' | System | 23 Sep 2020 14:39:25 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:52:25

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| User entered '23/Sep/2020 10:39' | System | 23 Sep 2020 14:39:25 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:52:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 15:16:05 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| | | |
| User entered 'I' | (b) (4), (b) (6) | 23 Sep 2020 14:39:25 |
| | | |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'USA-US072-2020-MRNA-1273-P301000003' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

Serious

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'Yes (Y)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Death](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'No (N)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Life threatening](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'No (N)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'Yes (Y)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'No (N)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'No (N)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Other medically important event](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'No (N)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'Douglas' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'Denham' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered '7940 Floyd Curl Drive' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'San Antonio' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

Site Address: [State](#)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:01:20 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Nov 2020 14:02:27 |
| Un-reviewed for Safety. | System | 14 Oct 2020 15:16:12 |
| User entered empty. | System | 14 Oct 2020 15:16:12 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 15:16:05 |
| User entered 'Texas' | Victoria Hernandez (b) (4) | 13 Oct 2020 20:46:47 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered '78229' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Investigator Country](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 15:16:05 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| | | |
| User entered 'US' | System | 23 Sep 2020 14:39:25 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 06 Nov 2020 13:14:38 |
| User entered '3' | System | 05 Nov 2020 14:02:37 |
| User entered '2' | System | 14 Oct 2020 15:16:12 |
| User entered '1' | System | 23 Sep 2020 14:39:25 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:52:25

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '14/Oct/2020 11:16' | System | 14 Oct 2020 15:16:12 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:52:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Nov 2020 14:02:27 |
| | | |
| User entered 'I' | (b) (4), (b) (6) | 14 Oct 2020 15:16:12 |
| | | |
| | | |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'USA-US072-2020-MRNA-1273-P301000003' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

Serious

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'Yes (Y)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Death](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'No (N)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Life threatening](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'No (N)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'Yes (Y)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'No (N)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'No (N)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Other medically important event](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'No (N)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'Douglas' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'Denham' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered '7940 Floyd Curl Drive' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'San Antonio' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

Site Address: [State](#)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:01:20 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Nov 2020 14:02:27 |
| Un-reviewed for Safety. | System | 14 Oct 2020 15:16:12 |
| User entered empty. | System | 14 Oct 2020 15:16:12 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 15:16:05 |
| User entered 'Texas' | Victoria Hernandez (b) (4) | 13 Oct 2020 20:46:47 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered '78229' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Investigator Country](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 15:16:05 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| | | |
| User entered 'US' | System | 23 Sep 2020 14:39:25 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 06 Nov 2020 13:14:38 |
| User entered '3' | System | 05 Nov 2020 14:02:37 |
| User entered '2' | System | 14 Oct 2020 15:16:12 |
| User entered '1' | System | 23 Sep 2020 14:39:25 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:52:25

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '05/Nov/2020 09:02' | System | 05 Nov 2020 14:02:37 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:52:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 06 Nov 2020 13:14:29 |
| User entered 'I' | (b) (4), (b) (6) | 05 Nov 2020 14:02:37 |
| | | |
| | | |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'USA-US072-2020-MRNA-1273-P301000003' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

Serious

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'Yes (Y)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Death](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'No (N)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Life threatening](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'No (N)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'Yes (Y)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'No (N)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'No (N)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Other medically important event](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'No (N)' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'Douglas' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'Denham' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered '7940 Floyd Curl Drive' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered 'San Antonio' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

Site Address: [State](#)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 19:01:20 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Nov 2020 14:02:27 |
| Un-reviewed for Safety. | System | 14 Oct 2020 15:16:12 |
| User entered empty. | System | 14 Oct 2020 15:16:12 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 15:16:05 |
| User entered 'Texas' | Victoria Hernandez (b) (4) | 13 Oct 2020 20:46:47 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 14:39:18 |
| User entered '78229' | System | 23 Sep 2020 14:38:57 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Investigator Country](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 15:16:05 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Oct 2020 20:58:22 |
| | | |
| User entered 'US' | System | 23 Sep 2020 14:39:25 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 06 Nov 2020 13:14:38 |
| User entered '3' | System | 05 Nov 2020 14:02:37 |
| User entered '2' | System | 14 Oct 2020 15:16:12 |
| User entered '1' | System | 23 Sep 2020 14:39:25 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:52:25

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '06/Nov/2020 13:14' | System | 06 Nov 2020 13:14:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:52:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered 'I' | (b) (4), (b) (6) | 06 Nov 2020 13:14:38 |
| | | |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered 'USA-US072-2020-MRNA-1273-P301000014' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

Serious

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered 'No (N)' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Death](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered 'No (N)' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Life threatening](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered 'No (N)' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered 'No (N)' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered 'No (N)' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered 'No (N)' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Other medically important event](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered 'No (N)' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered 'Douglas' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered 'Denham' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered '7940 Floyd Curl Drive' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered 'San Antonio' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered '78229' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Investigator Country](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered 'US' | System | 24 Nov 2020 13:55:07 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 24 Nov 2020 13:55:07 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered 'USA-US072-2020-MRNA-1273-P301000014' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

Serious

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered 'No (N)' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Death](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered 'No (N)' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Life threatening](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered 'No (N)' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered 'No (N)' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered 'No (N)' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered 'No (N)' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Other medically important event](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered 'No (N)' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered 'Douglas' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered 'Denham' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered '7940 Floyd Curl Drive' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered 'San Antonio' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:54:58 |
| User entered '78229' | System | 24 Nov 2020 13:54:38 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[Investigator Country](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered 'US' | System | 24 Nov 2020 13:55:07 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 24 Nov 2020 13:55:07 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:52:25

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24/Nov/2020 13:55' | System | 24 Nov 2020 13:55:07 |

US3292320

Folder: SAE USA-US072-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:52:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered 'I' | (b) (4), (b) (6) | 24 Nov 2020 13:55:07 |
| | | |