

US3252127 (Prod: Centex Studies Inc)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:09:59

All time stamps listed in this document are displayed in GMT

US3252127

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 20:14:26

Generated On: 09 Jun 2021 16:09:59

[Participant ID](#)

US3252127

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

US3252127

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 11 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | SCRN |

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 04 Mar 2021 23:57:54

Generated On: 09 Jun 2021 16:09:59

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1952 |
| Age | 68 |
| Age Units | YEARS |
| Age (Derived) | 68 |
| Sex | Female <input type="radio"/> Male <input checked="" type="radio"/> |
| Ethnicity | Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/> |
| Race (Check All That Apply) | |
| White | True |
| Black | False |
| Asian | False |
| American Indian or Alaska Native | False |
| Native Hawaiian or other Pacific Islander | False |
| Other | False |
| If race is Other, specify _____ | |
| Unknown | False |
| Not reported | False |

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 04 Mar 2021 23:57:54

Generated On: 09 Jun 2021 16:09:59

| | |
|---|--|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 11 AUG 2020 |
| Month and Year of Informed Consent (derived) | AUG 2020 |
| Year of Informed Consent (derived) | 2020 |
| Protocol Version | Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, indicate reason for screen fail | Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/> |
| If reason for screen fail is Other, specify | |
| Was this participant screened previously? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If Yes, previous participant number | |
| Enrollment Trigger | 1 |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 04 Mar 2021 23:57:54

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 04 Mar 2021 23:57:55

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 04 Mar 2021 23:57:55

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

| | |
|---|--|
| Condition | ACQUIRED TRIGGER FINGER |
| Start date (dd MMM yyyy) | UN UNK 2017 |
| 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 2017 |
| Start Year (derived) | 2017 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

| | |
|---|--|
| Condition | GASTRITIS |
| 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)

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

| | |
|---|--|
| Condition | GENERAL CEREBRAL ATROPHY |
| Start date (dd MMM yyyy) | UN JUN 2020 |
| 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) | JUN 2020 |
| Start Year (derived) | 2020 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 04 Mar 2021 23:57:55

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

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Form: Medical History (12)

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

| | |
|---|--|
| Condition | CHRONIC KIDNEY DISEASE STAGE 3 |
| 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 (13)

Data signed: (b) (4) 04 Mar 2021 23:57:55

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

| | |
|---|--|
| Condition | VITAMION D DEFI |
| Start date (dd MMM yyyy) | UN UNK 2017 |
| 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 2017 |
| Start Year (derived) | 2017 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

| | |
|---|--|
| Condition | ENDOSCOPY |
| Start date (dd MMM yyyy) | UN JAN 2020 |
| 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 JAN 2020 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2020 |
| Start Year (derived) | 2020 |
| Stop Month and Year (derived) | JAN 2020 |
| Stop Year (derived) | 2020 |

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

| | |
|---|--|
| Condition | COLONOSCOPY |
| Start date (dd MMM yyyy) | UN AUG 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 AUG 2018 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | AUG 2018 |
| Start Year (derived) | 2018 |
| Stop Month and Year (derived) | AUG 2018 |
| Stop Year (derived) | 2018 |

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

| | |
|---|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 11 AUG 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 16:04 (24 HR) |
| Vital Signs Date and Time (derived) | 11 AUG 2020 16:04 |
| Height (<i>xxx.x</i>) | 68.7 in |
| Weight (<i>xxx.x</i>) | 199 lb |
| BMI (<i>xxx.x</i>) | 29.70636 kg/m ² |
| BMI units | KG/M2 |
| Temperature (<i>xxx.x</i>) | ND - Not Done |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | ND - Not Done |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | ND - Not Done |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | ND - Not Done |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | ND - Not Done |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 04 Mar 2021 23:57:55

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 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: Pregnancy Test

Data signed: (b) (4) 04 Mar 2021 23:57:55

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Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 04 Mar 2021 23:57:55

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify RETIRED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

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

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 11 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT1 |

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 185790

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 11 AUG 2020 |
| Time of assessment (00:00-23:59) | 16:04 (24 HR) |
| Vital Signs Date and Time (derived) | 11 AUG 2020 16:04 |
| Temperature (xxx.x) | 98.1 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 75 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 15 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 143 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 73 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

| | |
|-------------------------------------|---|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/> |
| Were vital signs assessed? | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| Date of assessment (dd MMM yyyy) | 11 AUG 2020 |
| Time of assessment (00:00-23:59) | 18:24 (24 HR) |
| Vital Signs Date and Time (derived) | 11 AUG 2020 18:24 |
| Temperature (xxx.x) | 97.5 F |
| Route of measurement | Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 75 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 155 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 75 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☐

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 04 Mar 2021 23:57:55

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Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 11 AUG 2020

What was the treatment time? (00:00-23:59) 17:34 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 17:34

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 11 AUG 2020 |
| Collection time (00:00-23:59) | 17:16 (24 HR) |
| Collection date and time (derived) | 11 AUG 2020 17:16 |

US3252127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 11 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 17:00 | 11 AUG 2020 17:00 |
| Nasopharyngeal Swab 2 | No | | |

US3252127

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 18:27

PC Open Date & Time

11 AUG 2020 17:54

PC Close Date & Time

11 AUG 2020 20:24

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 12 AUG 2020 11:41 |
| PC Open Date & Time | 11 AUG 2020 21:19 |
| PC Close Date & Time | 12 AUG 2020 11:59 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 00:17

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °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

13 AUG 2020 19:34

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

14 AUG 2020 20:04

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

15 AUG 2020 23:30

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 6

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

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

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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

16 AUG 2020 22:08

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 7

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

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

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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

17 AUG 2020 19:57

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

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

11 AUG 2020 18:35

PC Open Date & Time

11 AUG 2020 17:54

PC Close Date & Time

11 AUG 2020 20:24

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 11:43

PC Open Date & Time

11 AUG 2020 21:19

PC Close Date & Time

12 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 00:18

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 19:34

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 20:05

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

15 AUG 2020 23:31

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 22:09

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 19:58

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 11 AUG 2020 18:35 |
| PC Open Date & Time | 11 AUG 2020 17:54 |
| PC Close Date & Time | 11 AUG 2020 20:24 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 12 AUG 2020 11:44 |
| PC Open Date & Time | 11 AUG 2020 21:19 |
| PC Close Date & Time | 12 AUG 2020 11:59 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 13 AUG 2020 00:19 |
| PC Open Date & Time | 12 AUG 2020 12:00 |
| PC Close Date & Time | 13 AUG 2020 11:59 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

62 of 2591

EAB) (1725)

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 13 AUG 2020 19:36 |
| PC Open Date & Time | 13 AUG 2020 12:00 |
| PC Close Date & Time | 14 AUG 2020 11:59 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

64 of 2591

EAB) (1725)

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 14 AUG 2020 20:05 |
| PC Open Date & Time | 14 AUG 2020 12:00 |
| PC Close Date & Time | 15 AUG 2020 11:59 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 15 AUG 2020 23:31 |
| PC Open Date & Time | 15 AUG 2020 12:00 |
| PC Close Date & Time | 16 AUG 2020 11:59 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 16 AUG 2020 22:09 |
| PC Open Date & Time | 16 AUG 2020 12:00 |
| PC Close Date & Time | 17 AUG 2020 11:59 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 17 AUG 2020 19:59 |
| PC Open Date & Time | 17 AUG 2020 12:00 |
| PC Close Date & Time | 18 AUG 2020 11:59 |

US3252127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 04 Mar 2021 23:57:54

Generated On: 09 Jun 2021 16:09:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252127

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 04 Mar 2021 23:57:54

Generated On: 09 Jun 2021 16:09:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 04 Mar 2021 23:57:54

Generated On: 09 Jun 2021 16:09:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252127

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 04 Mar 2021 23:57:54

Generated On: 09 Jun 2021 16:09:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 04 Mar 2021 23:57:54

Generated On: 09 Jun 2021 16:09:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252127

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 04 Mar 2021 23:57:54

Generated On: 09 Jun 2021 16:09:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

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

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

| | |
|-------------------------------------|---|
| Timepoint | Pre-Dose <input checked="" type="radio"/> |
| | Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 8 SEP 2020 |
| Time of assessment (00:00-23:59) | 15:39 (24 HR) |
| Vital Signs Date and Time (derived) | 8 SEP 2020 15:39 |
| Temperature (xxx.x) | 97.5 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 74 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 120 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 67 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

| | |
|-------------------------------------|---|
| Timepoint | Pre-Dose <input type="checkbox"/> |
| | Post-Dose <input checked="" type="checkbox"/> |
| Were vital signs assessed? | Yes <input checked="" type="checkbox"/> |
| | No <input type="checkbox"/> |
| Date of assessment (dd MMM yyyy) | 8 SEP 2020 |
| Time of assessment (00:00-23:59) | 16:41 (24 HR) |
| Vital Signs Date and Time (derived) | 8 SEP 2020 16:41 |
| Temperature (xxx.x) | 98.1 F |
| Route of measurement | Oral <input checked="" type="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 69 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 15 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 128 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 66 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3252127

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☐

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3252127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 8 SEP 2020

What was the treatment time? (00:00-23:59) 16:09 (24 HR)

Treatment Date and Time (derived) 8 SEP 2020 16:09

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3252127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

| | |
|--|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (<i>dd MMM yyyy</i>) | 8 SEP 2020 |
| Collection time (<i>00:00-23:59</i>) | 16:06 (24 HR) |
| Collection date and time (derived) | 8 SEP 2020 16:06 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 8 SEP 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 16:00 | 8 SEP 2020 16:00 |
| Nasopharyngeal Swab 2 | No | | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

08 SEP 2020 16:44

PC Open Date & Time

08 SEP 2020 16:29

PC Close Date & Time

08 SEP 2020 18:59

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.0 °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 | 09 SEP 2020 00:47 |
| PC Open Date & Time | 08 SEP 2020 19:54 |
| PC Close Date & Time | 09 SEP 2020 11:59 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

| | |
|-------------------------------|--------------------------------------|
| Was TEMPERATURE taken? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

| | |
|---|---------|
| Please record your TEMPERATURE in °F | 98.9 °F |
|---|---------|

| | |
|--|--------------------------------------|
| Was any MEDICATION TAKEN today for pain or fever? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

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

| | |
|---|------|
| To TREAT pain or fever that has already occurred | True |
|---|------|

| | |
|--|------|
| To PREVENT pain or fever from occurring | True |
|--|------|

| | |
|---------------|-------------------|
| PC Time Stamp | 09 SEP 2020 21:58 |
|---------------|-------------------|

| | |
|---------------------|-------------------|
| PC Open Date & Time | 09 SEP 2020 12:00 |
|---------------------|-------------------|

| | |
|----------------------|-------------------|
| PC Close Date & Time | 10 SEP 2020 11:59 |
|----------------------|-------------------|

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

| | |
|--|--------------------------------------|
| Was TEMPERATURE taken? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Please record your TEMPERATURE in °F | 97.0 °F |
| Was any MEDICATION TAKEN today for pain or fever? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

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

| | |
|---|-------|
| To TREAT pain or fever that has already occurred | True |
| To PREVENT pain or fever from occurring | False |

| | |
|----------------------|-------------------|
| PC Time Stamp | 11 SEP 2020 09:45 |
| PC Open Date & Time | 10 SEP 2020 12:00 |
| PC Close Date & Time | 11 SEP 2020 11:59 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 10:32

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °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

13 SEP 2020 02:28

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

15 SEP 2020 09:55

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 16:45

PC Open Date & Time

08 SEP 2020 16:29

PC Close Date & Time

08 SEP 2020 18:59

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 00:48

PC Open Date & Time

08 SEP 2020 19:54

PC Close Date & Time

09 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 21:58

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 09:46

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 10:33

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

13 SEP 2020 02:28

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 09:56

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 08 SEP 2020 16:45 |
| PC Open Date & Time | 08 SEP 2020 16:29 |
| PC Close Date & Time | 08 SEP 2020 18:59 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 09 SEP 2020 00:49 |
| PC Open Date & Time | 08 SEP 2020 19:54 |
| PC Close Date & Time | 09 SEP 2020 11:59 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 09 SEP 2020 22:00 |
| PC Open Date & Time | 09 SEP 2020 12:00 |
| PC Close Date & Time | 10 SEP 2020 11:59 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 11 SEP 2020 09:47 |
| PC Open Date & Time | 10 SEP 2020 12:00 |
| PC Close Date & Time | 11 SEP 2020 11:59 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 12 SEP 2020 10:33 |
| PC Open Date & Time | 11 SEP 2020 12:00 |
| PC Close Date & Time | 12 SEP 2020 11:59 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 13 SEP 2020 02:29 |
| PC Open Date & Time | 12 SEP 2020 12:00 |
| PC Close Date & Time | 13 SEP 2020 11:59 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

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US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

Yes ☐

PC Time stamp

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 15 SEP 2020 09:56 |
| PC Open Date & Time | 14 SEP 2020 12:00 |
| PC Close Date & Time | 15 SEP 2020 11:59 |

US3252127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 04 Mar 2021 23:57:54

Generated On: 09 Jun 2021 16:09:59

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

US3252127

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 04 Mar 2021 23:57:54

Generated On: 09 Jun 2021 16:09:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 04 Mar 2021 23:57:54

Generated On: 09 Jun 2021 16:09:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252127

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 04 Mar 2021 23:57:54

Generated On: 09 Jun 2021 16:09:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 04 Mar 2021 23:57:54

Generated On: 09 Jun 2021 16:09:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252127

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 04 Mar 2021 23:57:54

Generated On: 09 Jun 2021 16:09:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 7 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 |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

| | |
|---|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 7 OCT 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 15:29 (24 HR) |
| Vital Signs Date and Time (derived) | 7 OCT 2020 15:29 |
| Temperature (<i>xxx.x</i>) | 97.6 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | 68 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | 124 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | 68 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 OCT 2020

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

US3252127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 7 OCT 2020 |
| Collection time (00:00-23:59) | 15:56 (24 HR) |
| Collection date and time (derived) | 7 OCT 2020 15:56 |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 04 Mar 2021 23:57:55

Generated On: 09 Jun 2021 16:09:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

| | |
|---|--|
| TIMEPOINT | DAY 64 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 14 OCT 2020 18:57:12 |
| Patient Cloud Open Date & Time | 11 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 15 OCT 2020 23:59 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 12:18:01

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 11:38:35

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

| TIMEPOINT | DAY 92 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature \geq 100.4°F/38°C) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

| TIMEPOINT | DAY 99 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature \geq 100.4°F/38°C) | False |
| Chills | True |
| Cough | False |
| Shortness of breath | True |
| Difficulty breathing | False |
| Fatigue | True |
| Muscle aches | False |
| Body aches | False |
| Headache | False |
| New loss of taste | False |
| New loss of smell | False |
| Sore throat | False |
| Congestion | False |
| Runny nose | False |
| Nausea | False |
| Vomiting | False |
| Diarrhea | False |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission | 15 NOV 2020 15:52:24 |
| Patient Cloud Open Date & Time | 15 NOV 2020 00:01 |
| PRODUCTION RELEASE (v12.003 EAB) (1725) | |
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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

19 NOV 2020 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 14:29:22

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 17:55:41

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 18:42:13

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

13 DEC 2020 10:49:44

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 14:02:33

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 20:37:28

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

| TIMEPOINT | DAY 145 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature \geq 100.4°F/38°C) | False |
| Chills | True |
| Cough | False |
| Shortness of breath | False |
| Difficulty breathing | False |
| Fatigue | False |
| Muscle aches | False |
| Body aches | False |
| Headache | False |
| New loss of taste | False |
| New loss of smell | False |
| Sore throat | False |
| Congestion | False |
| Runny nose | False |
| Nausea | False |
| Vomiting | False |
| Diarrhea | False |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Date and time of submission | 03 JAN 2021 13:06:34 |
| Patient Cloud Open Date & Time | 31 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 04 JAN 2021 23:59 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 JAN 2021 08:59:27

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 10:21:59

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 JAN 2021 15:07:20

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 13:21:36

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 16:02:59

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 12:09:12

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 10:03:36

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 17:49:26

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 14:45:56

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 14:05:47

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 09:22:03

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 14:54:47

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 19:18:59

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 22:50:05

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 14:05:58

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 21:31:56

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAY 2021 23:19:02

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 271

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 13 MAY 2021 00:01 |
| Patient Cloud Close Date & Time | 17 MAY 2021 23:59 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 292

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 299

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 306

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 320

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 327

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

| TIMEPOINT | DAY 341 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 15 JUL 2021 00:01 |
| Patient Cloud Close Date & Time | 19 JUL 2021 23:59 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 348

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 355

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 362

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

| | |
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| Patient Cloud Open Date & Time | 12 AUG 2021 00:01 |
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|---|-------------------|
| Patient Cloud Close Date & Time | 16 AUG 2021 23:59 |
|---|-------------------|

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 383

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 02 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 06 SEP 2021 23:59 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 397

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

| TIMEPOINT | DAY 404 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

| TIMEPOINT | DAY 411 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 418

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

| TIMEPOINT | DAY 425 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 07 OCT 2021 00:01 |
| Patient Cloud Close Date & Time | 11 OCT 2021 23:59 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 432

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 439

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 21 OCT 2021 00:01 |
|--|-------------------|

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 25 OCT 2021 23:59 |
|---|-------------------|

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

| TIMEPOINT | DAY 446 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 453

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

| TIMEPOINT | DAY 460 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 467

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 481

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 02 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 06 DEC 2021 23:59 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 488

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 09 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 13 DEC 2021 23:59 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

| TIMEPOINT | DAY 495 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3252127

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| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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| Date and time of submission | |
| Patient Cloud Open Date & Time | 16 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 20 DEC 2021 23:59 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 30 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 03 JAN 2022 23:59 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 523

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 27 JAN 2022 00:01 |
| Patient Cloud Close Date & Time | 31 JAN 2022 23:59 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 572

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 579

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

| TIMEPOINT | DAY 600 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature \geq 100.4°F/38°C) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

| TIMEPOINT | DAY 607 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <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"/> |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

| TIMEPOINT | DAY 614 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 14 APR 2022 00:01 |
| Patient Cloud Close Date & Time | 18 APR 2022 23:59 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

| TIMEPOINT | DAY 621 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 21 APR 2022 00:01 |
| Patient Cloud Close Date & Time | 25 APR 2022 23:59 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 628

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 635

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 642

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 649

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 656

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 26 MAY 2022 00:01 |
| Patient Cloud Close Date & Time | 30 MAY 2022 23:59 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 677

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

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

No ☐

Yes ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 684

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

| TIMEPOINT | DAY 691 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 30 JUN 2022 00:01 |
| Patient Cloud Close Date & Time | 04 JUL 2022 23:59 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 712

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 21 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 25 JUL 2022 23:59 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 719

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 726

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 733

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

| TIMEPOINT | DAY 740 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 747

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 25 AUG 2022 00:01 |
|--|-------------------|

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 29 AUG 2022 23:59 |
|---|-------------------|

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

| TIMEPOINT | DAY 768 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <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"/> |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 782

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

DAY 789

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

| TIMEPOINT | DAY 796 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

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

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

US3252127

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:09:59

| Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other? | Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache? | Date & Time of Submission |
|---|--|---------------------------|
| No | | 27 FEB 2021 17:50:26 |

US3252127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:14:28

Generated On: 09 Jun 2021 16:09:59

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3252127

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:14:28

Generated On: 09 Jun 2021 16:09:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252127

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:14:28

Generated On: 09 Jun 2021 16:09:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252127

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:14:28

Generated On: 09 Jun 2021 16:09:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252127

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:14:28

Generated On: 09 Jun 2021 16:09:59

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 6 JAN 2021

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

Comments LEFT VOICE MAIL

If Contact Not Made, please provide Comments

US3252127

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:14:28

Generated On: 09 Jun 2021 16:09:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252127

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:14:28

Generated On: 09 Jun 2021 16:09:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252127

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:14:28

Generated On: 09 Jun 2021 16:09:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252127

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 19:48:46

Generated On: 09 Jun 2021 16:09:59

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

US3252127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 19:48:46

Generated On: 09 Jun 2021 16:09:59

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3252127

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 19:48:46

Generated On: 09 Jun 2021 16:09:59

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3252127

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 19:48:46

Generated On: 09 Jun 2021 16:09:59

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 8 MAR 2021 |
| Collection time (00:00-23:59) | 15:26 (24 HR) |
| Collection date and time (derived) | 8 MAR 2021 15:26 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 19:48:46

Generated On: 09 Jun 2021 16:09:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252127

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 02:03:57

Generated On: 09 Jun 2021 16:09:59

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 6 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3252127

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 02:03:57

Generated On: 09 Jun 2021 16:09:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252127

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252127

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | |
|--|---|
| Date of Contact | 05 JAN 2021 |
| Time of Contact | 09:52 |
| Date and Time of Contact (derived) | 05 JAN 2021 09:52 |
| Type of Contact | Clinic Visit - Scheduled <input checked="" type="radio"/> |
| | Clinical Visit - Unscheduled <input type="radio"/> |
| | Safety Call <input type="radio"/> |
| | Convalescent Tele-visit <input type="radio"/> |
| Has the subject reported symptoms of SARS-COV-2? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

Symptom Day

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

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | | |
|----------------------|-------------|-------------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | 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 | 05 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 98.8 F | |
| 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 checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

333 of 2591

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input 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 checked="" type="radio"/> |
| | Mild | <input 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"/> |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| 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 checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

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"/> |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | 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 | 06 JAN 2021 |
|------|-------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|------|
| O2 Saturation | 97 % |
|---------------|------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|--------|
| Temperature | 97.4 F |
|-------------|--------|

| | | |
|--------|----------|-------------------------------------|
| 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 checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input 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 checked="" type="radio"/> |
| | Mild | <input 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"/> |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| 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 checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

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"/> |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | 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 | 07 JAN 2021 |
|------|-------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|------|
| O2 Saturation | 99 % |
|---------------|------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|------|
| Temperature | 97 F |
|-------------|------|

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

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input 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 checked="" type="radio"/> |
| | Mild | <input 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"/> |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| 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 checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

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"/> |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | 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 | 8 JAN 2021 |
|------|------------|

| | |
|---------------------|------|
| Assessment Not Done | True |
|---------------------|------|

| | |
|---------------|----------------------|
| O2 Saturation | <input type="text"/> |
|---------------|----------------------|

| | |
|---------------------|----------------------|
| O2 Saturation Units | <input type="text"/> |
|---------------------|----------------------|

| | |
|-------------|----------------------|
| Temperature | <input type="text"/> |
|-------------|----------------------|

| | | |
|--------|----------|--------------------------|
| Chills | None | <input type="checkbox"/> |
| | Mild | <input 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"/> |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | | |
|------------------------|----------|--------------------------|
| | Not Done | <input type="checkbox"/> |
| Fatigue | None | <input type="checkbox"/> |
| | 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 type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Headache | None | <input type="checkbox"/> |
| | Mild | <input 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"/> |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | | |
|-------------------------|----------|--------------------------|
| Nasal Congestion | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | 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 05 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

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"/> |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | 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 | 9 JAN 2021 |
|------|------------|

| | |
|---------------------|------|
| Assessment Not Done | True |
|---------------------|------|

| | |
|---------------|----------------------|
| O2 Saturation | <input type="text"/> |
|---------------|----------------------|

| | |
|---------------------|----------------------|
| O2 Saturation Units | <input type="text"/> |
|---------------------|----------------------|

| | |
|-------------|----------------------|
| Temperature | <input type="text"/> |
|-------------|----------------------|

| | | |
|--------|----------|--------------------------|
| Chills | None | <input type="checkbox"/> |
| | Mild | <input 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"/> |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | | |
|------------------------|----------|--------------------------|
| | Not Done | <input type="checkbox"/> |
| Fatigue | None | <input type="checkbox"/> |
| | 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 type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Headache | None | <input type="checkbox"/> |
| | Mild | <input 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"/> |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | | |
|-------------------------|----------|--------------------------|
| Nasal Congestion | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | 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"/> |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

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"/> |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | 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 | 10 JAN 2021 |
|------|-------------|

| | |
|---------------------|------|
| Assessment Not Done | True |
|---------------------|------|

| | |
|---------------|----------------------|
| O2 Saturation | <input type="text"/> |
|---------------|----------------------|

| | |
|---------------------|----------------------|
| O2 Saturation Units | <input type="text"/> |
|---------------------|----------------------|

| | |
|-------------|----------------------|
| Temperature | <input type="text"/> |
|-------------|----------------------|

| | | |
|--------|----------|--------------------------|
| Chills | None | <input type="checkbox"/> |
| | Mild | <input 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | | |
|------------------------|----------|--------------------------|
| | Not Done | <input type="checkbox"/> |
| Fatigue | None | <input type="checkbox"/> |
| | 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 type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Headache | None | <input type="checkbox"/> |
| | Mild | <input 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"/> |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | | |
|-------------------------|----------|--------------------------|
| Nasal Congestion | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | 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"/> |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

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"/> |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | 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 | 11 JAN 2021 |
|------|-------------|

| | |
|---------------------|------|
| Assessment Not Done | True |
|---------------------|------|

| | |
|---------------|----------------------|
| O2 Saturation | <input type="text"/> |
|---------------|----------------------|

| | |
|---------------------|----------------------|
| O2 Saturation Units | <input type="text"/> |
|---------------------|----------------------|

| | |
|-------------|----------------------|
| Temperature | <input type="text"/> |
|-------------|----------------------|

| | | |
|--------|----------|--------------------------|
| Chills | None | <input type="checkbox"/> |
| | Mild | <input 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"/> |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | | |
|------------------------|----------|--------------------------|
| | Not Done | <input type="checkbox"/> |
| Fatigue | None | <input type="checkbox"/> |
| | 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 type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Headache | None | <input type="checkbox"/> |
| | Mild | <input 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"/> |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | | |
|-------------------------|----------|--------------------------|
| Nasal Congestion | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | 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"/> |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | |
|---|--|
| Date of Visit | 05 JAN 2021 |
| 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 type="radio"/> No <input checked="" type="radio"/> |
| Date of Test | 05 JAN 2021 |
| 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) | 0 |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3252127

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 22 Apr 2021 18:47:25

Generated On: 09 Jun 2021 16:09:59

| Visit | Was Saliva Collected? | Date of Collection |
|--------|-----------------------|--------------------|
| Day 3 | Yes | 07 JAN 2021 |
| Day 5 | Yes | 09 JAN 2021 |
| Day 7 | No | |
| Day 9 | No | |
| Day 14 | No | |
| Day 21 | No | |
| Day 28 | No | |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 05 JAN 2021 |
|--------------------------|-------------|

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

| | |
|------------|--------|
| Folder OID | SICKD1 |
|------------|--------|

US3252127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | |
|---|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 05 JAN 2021 |
| Time of assessment (<i>00:00-23:59</i>) | 09:44 (24 HR) |
| Vital Signs Date and Time (derived) | 05 JAN 2021 09:44 |
| Height (<i>xxx.x</i>) | 68.7 in |
| Weight (<i>xxx.x</i>) | 199 lb |
| Temperature (<i>xxx.x</i>) | 98.8 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | 76 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 15 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | 129 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | 75 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 JAN 2021

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

US3252127

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

05 JAN 2021

US3252127

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 22 JAN 2021 |
|--------------------------|-------------|

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

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

US3252127

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 19:48:45

Generated On: 09 Jun 2021 16:09:59

Date of updated informed consent (*dd MMM yyyy*) 22 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (*dd MMM yyyy*) 22 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3252127

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 JAN 2021

Collection time (00:00-23:59)

11:40 (24 HR)

Collection date and time (derived)

22 JAN 2021 11:40

US3252127

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 22 JAN 2021 |
| Collection time (00:00 - 23:59) | 11:40 |
| Collection Date and Time (derived) | 22 JAN 2021 11:40 |

US3252127

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 20:14:26

Generated On: 09 Jun 2021 16:09:59

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 05 Mar 2021 20:14:26

Generated On: 09 Jun 2021 16:09:59

| | |
|--|--|
| AEID | USA-US108-2020-MRNA-1273-P30 1000013 |
| Adverse event | APPENDICITIS |
| 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) | 28 OCT 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 29 OCT 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 28 OCT 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 29 OCT 2020 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |

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Folder: Adverse Events

Form: Adverse Events (2)

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| | |
|--|---|
| Number of Days in ICU | |
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | 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 | PATIENT PRESENTED WITH APPENDICITIS ON OCTOBER 28TH, GOT OPERATED THE SAME DAY AND GOT DISCHARGED ON OCTOBER 29TH. |
| Serious Adverse Event Derived (CSA Programming Field Only) | 1 |

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Folder: Adverse Events

Form: Adverse Events (2)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 20:14:27

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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Name of Medication FENOFIBERATE

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEREMIA

Dose per administration 134

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 20:14:26

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Name of Medication MONTELUKAST

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 20:14:26

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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Name of Medication PRAVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROL

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 20:14:26

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Mar 2021 20:14:26

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Name of Medication DOXAZOSIN MESYLATE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Mar 2021 20:14:26

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Mar 2021 20:14:26

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Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Mar 2021 20:14:26

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2010 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 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 (6)

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Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2010 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 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 (7)

Data signed: (b) (4) 05 Mar 2021 20:14:26

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Name of Medication FINISTERIDE

Prophylaxis Yes ☐
No ☒

Indication ENLARGED PROSTATE

Dose per administration 5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☒
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN | UNK 2009 |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 2 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Mar 2021 20:14:26

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Name of Medication DICLOFENAC 1% TOPICAL GEL

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS OF HANDS

Dose per administration 2

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify APPLICATIONS

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Mar 2021 20:14:26

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2010 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____ | | |
| 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 (9)

Data signed: (b) (4) 05 Mar 2021 20:14:26

Generated On: 09 Jun 2021 16:09:59

Name of Medication LINZESS

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 72

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify MCG

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Mar 2021 20:14:26

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2019 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

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Name of Medication FLUTICASONE PROPIONATE

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 50

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify MCG

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input checked="" type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2010 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____ | | |
| 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 (11)

Data signed: (b) (4) 05 Mar 2021 20:14:26

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Name of Medication ZOLPIDEM

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Mar 2021 20:14:26

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2010 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

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Name of Medication EUTHYROX

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROID

Dose per administration 50

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify MCG

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Mar 2021 20:14:26

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2019 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Mar 2021 20:14:26

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Name of Medication MULTIVITAMINS

Prophylaxis Yes ☒
No ☐

Indication DIETARY SUPPLEMENT

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Mar 2021 20:14:26

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2009 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

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Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CAROTID ATHEROSCLEROSIS

Dose per administration 81

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2009 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Mar 2021 20:14:26

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Name of Medication BETA SITOSTEROL

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Mar 2021 20:14:26

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| | | |
|--|--------------------------|----------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN | UNK 2009 |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Mar 2021 20:14:26

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Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTRITIS

Dose per administration 40

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Mar 2021 20:14:26

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| | | |
|--|--------------------------|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 7 SEP 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 29 SEP 2020 | | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | | 1 |
| Interval Dosage Unit Number (derived) | | 1 |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 05 Mar 2021 20:14:26

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Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication PAIN IN INJECTION SITE

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☒
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

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| | | |
|--|--------------------------|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 9 SEP 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 11 SEP 2020 | |
| Was this medication taken for solicited event? | Yes | <input checked="" type="checkbox"/> |
| | No | <input type="checkbox"/> |
| Separate Dosage Number (derived) | 3 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 05 Mar 2021 20:14:26

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Name of Medication ESOMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTRITIS

Dose per administration 40

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 30 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 05 Mar 2021 20:14:26

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Name of Medication SUCRALFATE

Prophylaxis Yes ☐
No ☒

Indication GASTRITIS

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☒
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☒
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 30 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) | 4 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 05 Mar 2021 20:14:26

Generated On: 09 Jun 2021 16:09:59

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify INJECTION

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 05 Mar 2021 20:14:26

Generated On: 09 Jun 2021 16:09:59

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input checked="" type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 29 SEP 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 29 SEP 2020 |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 05 Mar 2021 20:14:26

Generated On: 09 Jun 2021 16:09:59

Name of Medication AMOXICILLIN/CLAVULANATE

Prophylaxis Yes ☐
No ☒

Indication APPENDICITIS

Dose per administration 500/125

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 05 Mar 2021 20:14:26

Generated On: 09 Jun 2021 16:09:59

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 29 OCT 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 2 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3252127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3252127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>) | Procedure/Surgery | Indication | If indication is Other, specify |
|---|-------------------|---------------|---------------------------------|
| 28 OCT 2020 | APPENDECTOMY | Adverse Event | |

US3252127

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:09:59

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3252127

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:09:59

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | |
|--|--|
| SAEID | USA-US108-2020-MRNA-1273-P301000013 |
| 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 | JOEL |
| Investigator's Last Name | SOLIS |
| Site Address: Street | 5201 N. 10TH STREET |
| Site Address: City | MCALLEN |
| Site Address: State | TX |
| Site Address: Postal Code | 78504 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 3 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | |
|---|--|
| SAEID | USA-US108-2020-MRNA-1273-P301000013 |
| 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 | JOEL |
| Investigator's Last Name | SOLIS |
| Site Address: Street | 5201 N. 10TH STREET |
| Site Address: City | MCALLEN |
| Site Address: State | TX |
| Site Address: Postal Code | 78504 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 3 |
| Date of submission (Pre-filled from custom function) | 04/NOV/2020 12:48 |
| 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 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | |
|---|--|
| SAEID | USA-US108-2020-MRNA-1273-P301000013 |
| 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 | JOEL |
| Investigator's Last Name | SOLIS |
| Site Address: Street | 5201 N. 10TH STREET |
| Site Address: City | MCALLEN |
| Site Address: State | TX |
| Site Address: Postal Code | 78504 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 3 |
| Date of submission (Pre-filled from custom function) | 23/NOV/2020 15:27 |
| 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 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Mar 2021 20:14:27

Generated On: 09 Jun 2021 16:09:59

| | |
|---|--|
| SAEID | USA-US108-2020-MRNA-1273-P301000013 |
| 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 | JOEL |
| Investigator's Last Name | SOLIS |
| Site Address: Street | 5201 N. 10TH STREET |
| Site Address: City | MCALLEN |
| Site Address: State | TX |
| Site Address: Postal Code | 78504 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 3 |
| Date of submission (Pre-filled from custom function) | 05/DEC/2020 13:20 |
| 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

US3252127 (Prod: Centex Studies Inc)

US3252127

Form: Participant Creation

Generated On: 09 Jun 2021 16:09:59

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'US3252127' | RWS_ENDPOINT ENDPOINT (b) (4) | 11 Aug 2020 20:59:23 |

US3252127

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:23:09 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '11 AUG 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 11 Aug 2020 20:59:24 |

US3252127

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Clinic (Clinic)' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:23:09 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'SCRN' | System | 11 Aug 2020 22:23:09 |

US3252127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:59

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered (b) (6) 1952' | RWS_ENDPOINT ENDPOINT (b) (4) | 11 Aug 2020 20:59:25 |

US3252127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:59

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '68' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:23:36 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:59

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'YEARS' | System | 11 Aug 2020 22:23:36 |

US3252127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:59

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered '68' | System | 11 Aug 2020 22:23:53 |

US3252127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:59

Sex

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Male (M)' reason for change: Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:02:37 |
| User entered 'Female (F)' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:23:36 |

US3252127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:59

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Hispanic or Latino (HISPANIC OR LATINO)' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:23:36 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:59

[White](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'I' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:23:36 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:59

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:23:36 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:59

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:23:36 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:59

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:23:36 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:59

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:23:36 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:59

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:23:36 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:59

If race is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Uche Ehiemua (b) (4) | 11 Aug 2020 22:23:36 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:59

[Unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:23:36 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:59

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:23:36 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:59

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '11 Aug 2020' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:23:53 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:59

[Month and Year of Informed Consent \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'Aug 2020' | System | 11 Aug 2020 22:23:53 |

US3252127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:59

[Year of Informed Consent \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered '2020' | System | 11 Aug 2020 22:23:53 |

US3252127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:59

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Amendment 2 (2)' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:23:53 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:59

[Was participant enrolled in the study?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:23:53 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:59

[If No, indicate reason for screen fail](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Uche Ehiemua (b) (4) | 11 Aug 2020 22:23:53 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:59

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Uche Ehiemua (b) (4) | 11 Aug 2020 22:23:53 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:59

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'No (N)' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:23:53 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:59

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | RWS_ENDPOINT ENDPOINT (b) (4) | 11 Aug 2020 20:59:24 |

US3252127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:59

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'I' | System | 11 Aug 2020 22:24:05 |

US3252127

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:09:59

[Did the participant meet all eligibility criteria?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:24:05 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:09:59

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:35:24 |

US3252127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:59

[Condition](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Aug 2020 18:38:09 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Aug 2020 18:38:09 |
| Data point term sent to Coder | System | 12 Aug 2020 18:37:03 |
| User entered 'Hypertension' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:37:01 |

US3252127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:59

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'UN UNK 2010' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:37:01 |

US3252127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:59

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:37:01 |

US3252127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:37:01 |

US3252127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:59

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:37:01 |

US3252127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:37:01 |

US3252127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:59

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'Jan 2010' | System | 12 Aug 2020 18:37:01 |

US3252127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:59

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered '2010' | System | 12 Aug 2020 18:37:01 |

US3252127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:59

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:37:01 |

US3252127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:59

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:37:01 |

US3252127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:59

[Condition](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0. | Coder Import (b) (4) | 04 Nov 2020 13:42:22 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | (b) (4) | 04 Nov 2020 13:42:22 |
| Data point term sent to Coder | System | 04 Nov 2020 13:41:24 |
| Coding entries removed. | Nancy Torrence (b) (4) | 04 Nov 2020 13:40:43 |
| | (b) (4) | |
| User entered 'Benign prostatic hyperplasia' reason for change: Data Entry Error | Nancy Torrence (b) (4) | 04 Nov 2020 13:40:43 |
| | (b) (4) | |
| User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatomegaly, LLT: Enlarged prostate - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Aug 2020 18:40:19 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Aug 2020 18:40:19 |
| | (b) (4) | |
| Data point term sent to Coder | System | 12 Aug 2020 18:39:13 |
| User entered 'Enlarged Prostate' | Joanna Gurrola Mahoney | 12 Aug 2020 18:38:35 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:59

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'UN UNK 2009' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:38:35 |

US3252127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:59

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:38:35 |

US3252127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:38:35 |

US3252127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:59

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:38:35 |

US3252127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:38:35 |

US3252127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:59

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'Jan 2009' | System | 12 Aug 2020 18:38:35 |

US3252127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:59

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered '2009' | System | 12 Aug 2020 18:38:35 |

US3252127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:59

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:38:35 |

US3252127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:59

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:38:35 |

US3252127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:59

[Condition](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Aug 2020 18:41:13 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | (b) (4) | 12 Aug 2020 18:41:13 |
| Data point term sent to Coder | System | 12 Aug 2020 18:40:15 |
| User entered 'Hypercholesterolemia' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:39:23 |

US3252127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:59

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'UN UNK 2010' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:39:23 |

US3252127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:39:23 |

US3252127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:39:23 |

US3252127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:59

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:39:23 |

US3252127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:39:23 |

US3252127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:59

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'Jan 2010' | System | 12 Aug 2020 18:39:23 |

US3252127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:59

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered '2010' | System | 12 Aug 2020 18:39:23 |

US3252127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:59

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:39:23 |

US3252127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:59

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:39:23 |

US3252127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:59

[Condition](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Tendon, ligament and cartilage disorders, HLT: Tendon disorders, PT: Trigger finger, LLT: Trigger finger (acquired) - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Aug 2020 21:36:14 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Aug 2020 21:36:14 |
| Data point term sent to Coder | System | 12 Aug 2020 18:40:17 |
| User entered 'Acquired trigger finger' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:39:58 |

US3252127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:59

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'UN UNK 2017' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:39:58 |

US3252127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:59

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:39:58 |

US3252127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:39:58 |

US3252127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:59

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:39:58 |

US3252127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:39:58 |

US3252127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:59

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'Jan 2017' | System | 12 Aug 2020 18:39:58 |

US3252127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:59

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered '2017' | System | 12 Aug 2020 18:39:58 |

US3252127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:59

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:39:58 |

US3252127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:59

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:39:58 |

US3252127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:09:59

[Condition](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Aug 2020 18:42:19 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Aug 2020 18:42:19 |
| Data point term sent to Coder | System | 12 Aug 2020 18:41:19 |
| User entered 'Hypothyroid' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:40:34 |

US3252127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:09:59

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'UN UNK 2019' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:40:34 |

US3252127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:09:59

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:40:34 |

US3252127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:09:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:40:34 |

US3252127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:09:59

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:40:34 |

US3252127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:09:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:40:34 |

US3252127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:09:59

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'Jan 2019' | System | 12 Aug 2020 18:40:34 |

US3252127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:09:59

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered '2019' | System | 12 Aug 2020 18:40:34 |

US3252127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:09:59

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:40:34 |

US3252127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:09:59

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:40:34 |

US3252127

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:09:59

[Condition](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Aug 2020 18:42:20 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Aug 2020 18:42:20 |
| Data point term sent to Coder | System | 12 Aug 2020 18:41:20 |
| User entered 'Asthma' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:41:04 |

US3252127

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:09:59

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'UN UNK 2010' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:41:04 |

US3252127

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:41:04 |

US3252127

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:09:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:41:04 |

US3252127

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:09:59

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:41:04 |

US3252127

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:09:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:41:04 |

US3252127

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:09:59

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'Jan 2010' | System | 12 Aug 2020 18:41:04 |

US3252127

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:09:59

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered '2010' | System | 12 Aug 2020 18:41:04 |

US3252127

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:09:59

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:41:04 |

US3252127

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:09:59

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:41:04 |

US3252127

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:09:59

[Condition](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal inflammatory conditions, HLT: Gastritis (excl infective), PT: Gastritis, LLT: Gastritis - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Aug 2020 18:44:10 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Aug 2020 18:44:10 |
| Data point term sent to Coder | System | 12 Aug 2020 18:43:27 |
| User entered 'Gastritis' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:43:23 |

US3252127

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:09:59

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'UN UNK 2018' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:43:23 |

US3252127

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:43:23 |

US3252127

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:09:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:43:23 |

US3252127

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:09:59

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:43:23 |

US3252127

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:09:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:43:23 |

US3252127

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:09:59

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'Jan 2018' | System | 12 Aug 2020 18:43:23 |

US3252127

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:09:59

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered '2018' | System | 12 Aug 2020 18:43:23 |

US3252127

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:09:59

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:43:23 |

US3252127

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:09:59

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:43:23 |

US3252127

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:09:59

[Condition](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system vascular disorders NEC, PT: Carotid arteriosclerosis, LLT: Carotid arteriosclerosis - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Aug 2020 22:15:15 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Aug 2020 22:15:15 |
| Data point term sent to Coder | System | 12 Aug 2020 18:44:28 |
| User entered 'Carotid atherosclerosis' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:44:25 |

US3252127

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:09:59

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'UN UNK 2009' reason for change: | Joanna Gurrola Mahoney | 02 Nov 2020 20:32:17 |
| Data Entry Error | (b) (4) | |
| User entered 'UN Jun 2020' | Joanna Gurrola Mahoney | 12 Aug 2020 18:44:25 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:44:25 |

US3252127

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:09:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:44:25 |

US3252127

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:09:59

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:44:25 |

US3252127

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:09:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:44:25 |

US3252127

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:09:59

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'Jan 2009' | System | 02 Nov 2020 20:32:17 |
| User entered 'Jun 2020' | System | 12 Aug 2020 18:44:25 |

US3252127

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:09:59

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered '2009' | System | 02 Nov 2020 20:32:17 |
| User entered '2020' | System | 12 Aug 2020 18:44:25 |

US3252127

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:09:59

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:44:25 |

US3252127

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:09:59

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:44:25 |

US3252127

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:09:59

Condition

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Per DM CLR: Please specify the type (decreased brain mass, loss of neurological function) of CEREBRAL ATROPHY. 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) | 10 Nov 2020 19:49:33 |
| User coded data point as SOC: Nervous system disorders, HLGT: Structural brain disorders, HLT: Structural brain disorders NEC, PT: Cerebral atrophy, LLT: Cerebral atrophy - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 16 Sep 2020 13:50:37 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 16 Sep 2020 13:50:37 |
| Data point term sent to Coder | System | 15 Sep 2020 22:09:09 |
| Query 'Per DM CLR: Please specify the type (decreased brain mass, loss of neurological function) of CEREBRAL ATROPHY. 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 'As per patient, patient mentioned that he just had general cerebral atrophy. ' (Site from DM). | (b) (4), (b) (6) | 15 Sep 2020 22:09:07 |
| Coding entries removed. | (b) (4), (b) (6) | 15 Sep 2020 22:08:43 |
| User entered 'GENERAL CEREBRAL ATROPHY' reason for change: Data Entry Error | | 15 Sep 2020 22:08:43 |
| User opened query 'Per DM CLR: Please specify the type (decreased brain mass, loss of neurological function) of CEREBRAL ATROPHY. 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). | | 15 Sep 2020 16:25:39 |
| User coded data point as SOC: Nervous system disorders, HLGT: Structural brain disorders, HLT: Structural brain disorders NEC, PT: Cerebral atrophy, LLT: Cerebral atrophy - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 12 Aug 2020 18:46:11 |

US3252127

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:09:59

Condition

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User coded data point as Term Coded data point by | Coder Import (b) (4) | 12 Aug 2020 18:46:11 |
| User: Coder System - version MedDRA\\23.0. | (b) (4) | |
| Data point term sent to Coder | System | 12 Aug 2020 18:45:30 |
| User entered 'Cerebral Atrophy' | Joanna Gurrola Mahoney | 12 Aug 2020 18:45:30 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:09:59

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'UN Jun 2020' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:45:30 |

US3252127

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:45:30 |

US3252127

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:09:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:45:30 |

US3252127

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:09:59

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:45:30 |

US3252127

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:09:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:45:30 |

US3252127

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:09:59

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'Jun 2020' | System | 12 Aug 2020 18:45:30 |

US3252127

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:09:59

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered '2020' | System | 12 Aug 2020 18:45:30 |

US3252127

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:09:59

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:45:30 |

US3252127

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:09:59

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:45:30 |

US3252127

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:09:59

[Condition](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Chronic sinusitis, LLT: Chronic sinusitis - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Aug 2020 18:48:12 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Aug 2020 18:48:12 |
| Data point term sent to Coder | System | 12 Aug 2020 18:47:33 |
| User entered 'Chronic Sinusitis' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:46:34 |

US3252127

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:09:59

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 20 Aug 2020 19:17:04 |
| User entered 'UN UNK 2015' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:17:04 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 12 Aug 2020 18:46:34 |
| User entered '00 UNK 2015' (non-conformant). | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:46:34 |

US3252127

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:46:34 |

US3252127

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:09:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:46:34 |

US3252127

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:09:59

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:46:34 |

US3252127

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:09:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:46:34 |

US3252127

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:09:59

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'Jan 2015' | System | 20 Aug 2020 19:17:04 |
| User entered empty. | System | 12 Aug 2020 18:46:34 |

US3252127

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:09:59

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered '2015' | System | 20 Aug 2020 19:17:04 |
| User entered empty. | System | 12 Aug 2020 18:46:34 |

US3252127

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:09:59

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:46:34 |

US3252127

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:09:59

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:46:34 |

US3252127

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:09:59

[Condition](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Chronic idiopathic constipation - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Aug 2020 18:48:12 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Aug 2020 18:48:12 |
| Data point term sent to Coder | System | 12 Aug 2020 18:47:37 |
| User entered 'Chronic Idiopathic Constipation' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:47:28 |

US3252127

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:09:59

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'UN UNK 2019' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:47:28 |

US3252127

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:09:59

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:47:28 |

US3252127

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:09:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:47:28 |

US3252127

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:09:59

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:47:28 |

US3252127

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:09:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:47:28 |

US3252127

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:09:59

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'Jan 2019' | System | 12 Aug 2020 18:47:28 |

US3252127

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:09:59

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered '2019' | System | 12 Aug 2020 18:47:28 |

US3252127

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:09:59

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:47:28 |

US3252127

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:09:59

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:47:28 |

US3252127

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:09:59

Condition

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease stage 3 - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Aug 2020 18:52:49 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Aug 2020 18:52:49 |
| Data point term sent to Coder | System | 12 Aug 2020 18:51:47 |
| User entered 'CHRONIC KIDNEY DISEASE STAGE 3' reason for change: Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:51:06 |
| Data point term sent to Coder | System | 12 Aug 2020 18:49:39 |
| User entered 'Chronic Kidnsy Disease Stage 3' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:48:42 |

US3252127

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:09:59

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'UN UNK 2018' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:48:42 |

US3252127

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:48:42 |

US3252127

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:09:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:48:42 |

US3252127

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:09:59

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:48:42 |

US3252127

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:09:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:48:42 |

US3252127

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:09:59

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'Jan 2018' | System | 12 Aug 2020 18:48:42 |

US3252127

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:09:59

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered '2018' | System | 12 Aug 2020 18:48:42 |

US3252127

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:09:59

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:48:42 |

US3252127

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:09:59

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:48:42 |

US3252127

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:09:59

Condition

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. 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) | 02 Nov 2020 21:54:30 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hand osteoarthritis - version MedDRA\\23.0. | Coder Import (b) (4) | 01 Oct 2020 21:16:53 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 01 Oct 2020 21:16:53 |
| Data point term sent to Coder | System | 01 Oct 2020 21:15:21 |
| Query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. 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 'DATA UPDATED ' (Site from DM). | (b) (4), (b) (6) | 01 Oct 2020 21:14:28 |
| Coding entries removed. | (b) (4), (b) (6) | 01 Oct 2020 21:14:23 |
| User entered 'OSTEOARTHRITIS OF HANDS' reason for change: Data Entry Error | | 01 Oct 2020 21:14:23 |
| User opened query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. 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). | | 15 Sep 2020 16:26:54 |
| 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) | 12 Aug 2020 18:50:19 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Aug 2020 18:50:19 |
| Data point term sent to Coder | System | 12 Aug 2020 18:49:42 |
| User entered 'Osteoarthritis' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:49:32 |

US3252127

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:09:59

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'UN UNK 2010' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:49:32 |

US3252127

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:49:32 |

US3252127

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:09:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:49:32 |

US3252127

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:09:59

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:49:32 |

US3252127

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:09:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:49:32 |

US3252127

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:09:59

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'Jan 2010' | System | 12 Aug 2020 18:49:32 |

US3252127

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:09:59

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered '2010' | System | 12 Aug 2020 18:49:32 |

US3252127

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:09:59

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:49:32 |

US3252127

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:09:59

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:49:32 |

US3252127

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:09:59

[Condition](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Aug 2020 18:52:08 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Aug 2020 18:52:08 |
| Data point term sent to Coder | System | 12 Aug 2020 18:50:45 |
| User entered 'Insomnia' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:50:02 |

US3252127

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:09:59

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'UN UNK 2010' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:50:02 |

US3252127

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:09:59

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:50:02 |

US3252127

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:09:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:50:02 |

US3252127

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:09:59

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:50:02 |

US3252127

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:09:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:50:02 |

US3252127

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:09:59

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'Jan 2010' | System | 12 Aug 2020 18:50:02 |

US3252127

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:09:59

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered '2010' | System | 12 Aug 2020 18:50:02 |

US3252127

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:09:59

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:50:02 |

US3252127

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:09:59

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:50:02 |

US3252127

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:09:59

[Condition](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0. | Coder Import (b) (4) | 17 Aug 2020 07:37:19 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 17 Aug 2020 07:37:19 |
| Data point term sent to Coder | System | 12 Aug 2020 18:50:46 |
| User entered 'Vitamion D Defi' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:50:36 |

US3252127

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:09:59

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'UN UNK 2017' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:50:36 |

US3252127

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:50:36 |

US3252127

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:09:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 20 Aug 2020 19:16:20 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 20 Aug 2020 19:16:20 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:16:20 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 12 Aug 2020 18:50:36 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:50:36 |

US3252127

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:09:59

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:50:36 |

US3252127

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:09:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:50:36 |

US3252127

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:09:59

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'Jan 2017' | System | 12 Aug 2020 18:50:36 |

US3252127

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:09:59

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered '2017' | System | 12 Aug 2020 18:50:36 |

US3252127

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:09:59

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:50:36 |

US3252127

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:09:59

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 18:50:36 |

US3252127

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:09:59

Condition

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 02 Nov 2020 21:54:45 |
| Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'INDICATION FOR THIS IS THE GASTRITIS. DATA HAS BEEN PROVIDED, THANK YOU ' (Site from DM). | (b) (4), (b) (6) | 01 Oct 2020 21:18:06 |
| User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 15 Sep 2020 16:27:22 |
| User coded data point as SOC: Investigations, HLGT: Investigations, imaging and histopathology procedures NEC, HLT: Imaging procedures NEC, PT: Endoscopy, LLT: Endoscopy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 20 Aug 2020 19:28:26 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 20 Aug 2020 19:28:26 |
| Data point term sent to Coder | System | 20 Aug 2020 19:27:43 |
| User entered 'ENDOSCOPY' | Shannon Moyer (b) (4) (b) (4) | 20 Aug 2020 19:27:37 |

US3252127

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:09:59

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'UN Jan 2020' | Shannon Moyer (b) (4) | 20 Aug 2020 19:27:37 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Shannon Moyer (b) (4) | 20 Aug 2020 19:27:37 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:09:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'No (N)' | Shannon Moyer (b) (4) | 20 Aug 2020 19:27:37 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:09:59

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'UN Jan 2020' | Shannon Moyer (b) (4) | 20 Aug 2020 19:27:37 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:09:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Shannon Moyer (b) (4) | 20 Aug 2020 19:27:37 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:09:59

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'Jan 2020' | System | 20 Aug 2020 19:27:37 |

US3252127

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:09:59

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered '2020' | System | 20 Aug 2020 19:27:37 |

US3252127

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:09:59

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'Jan 2020' | System | 20 Aug 2020 19:27:37 |

US3252127

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:09:59

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered '2020' | System | 20 Aug 2020 19:27:37 |

US3252127

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:09:59

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 02 Nov 2020 21:54:51 |
| Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'THIS WAS A REGULAR ROUTINE EXAM AS PER THE PATIENT. THANK YOU. ' (Site from DM). | (b) (4), (b) (6) | 01 Oct 2020 21:18:30 |
| User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 15 Sep 2020 16:27:46 |
| User coded data point as SOC: Investigations, HLG: Gastrointestinal investigations, HLT: Gastrointestinal and abdominal imaging procedures, PT: Colonoscopy, LLT: Colonoscopy - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 20 Aug 2020 19:29:19 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 20 Aug 2020 19:29:19 |
| Data point term sent to Coder | System | 20 Aug 2020 19:28:46 |
| User entered 'COLONOSCOPY' | Shannon Moyer (b) (4) (b) (4) | 20 Aug 2020 19:28:09 |

US3252127

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:09:59

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'UN Aug 2018' | Shannon Moyer (b) (4) | 20 Aug 2020 19:28:09 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Shannon Moyer (b) (4) | 20 Aug 2020 19:28:09 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:09:59

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'No (N)' | Shannon Moyer (b) (4) | 20 Aug 2020 19:28:09 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:09:59

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'UN Aug 2018' | Shannon Moyer (b) (4) | 20 Aug 2020 19:28:09 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:09:59

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Shannon Moyer (b) (4) | 20 Aug 2020 19:28:09 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:09:59

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'Aug 2018' | System | 20 Aug 2020 19:28:09 |

US3252127

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:09:59

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered '2018' | System | 20 Aug 2020 19:28:09 |

US3252127

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:09:59

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'Aug 2018' | System | 20 Aug 2020 19:28:09 |

US3252127

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:09:59

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered '2018' | System | 20 Aug 2020 19:28:09 |

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:54:51 |

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '11 Aug 2020' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:54:51 |

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '16:04' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:54:51 |

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered '11 Aug 2020 16:04' | System | 12 Aug 2020 18:54:51 |

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Height \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '68.7' in | Joanna Gurrola Mahoney | 12 Aug 2020 18:54:51 |
| DataPoint set to visible. | (b) (4) System | 11 Aug 2020 22:24:05 |

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Weight \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '199' lb | Joanna Gurrola Mahoney | 12 Aug 2020 18:54:51 |
| DataPoint set to visible. | (b) (4) System | 11 Aug 2020 22:24:05 |

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

BMI (xxx.x)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| Amendment Manager: User entered '29.70636' | System | 16 Sep 2020 23:52:39 |
| User entered '29.7' | System | 12 Aug 2020 18:54:51 |
| DataPoint set to visible. | System | 11 Aug 2020 22:24:05 |

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'kg/m2' | System | 12 Aug 2020 18:54:51 |
| DataPoint set to visible. | System | 11 Aug 2020 22:24:05 |

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:24:42 |
| User entered '98.1' F | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:54:51 |

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 24 Aug 2020 12:36:31 |
| Query 'Data is required. Please provide.' answered with 'ND' (Site from System). | Shannon Moyer (b) (4) | 20 Aug 2020 19:24:57 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 20 Aug 2020 19:24:42 |
| User entered empty; reason for change Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:24:42 |
| User entered 'Oral (Oral)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:54:51 |

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:54:51 |

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:24:42 |
| User entered '75' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:54:51 |

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'bpm' | System | 12 Aug 2020 18:54:51 |

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:24:42 |
| User entered '15' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:54:51 |

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'breaths/min' | System | 12 Aug 2020 18:54:51 |

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:24:42 |
| User entered '143' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:54:51 |

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'mmHg' | System | 12 Aug 2020 18:54:51 |

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:24:42 |
| User entered '73' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:54:51 |

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered 'mmHg' | System | 12 Aug 2020 18:54:51 |

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| | | |

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |

US3252127

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:59

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:56:32 |

US3252127

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:59

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 11 Sep 2020 14:37:35 |
| User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). | System | 09 Sep 2020 02:55:33 |
| User entered '11 Aug 2020' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 18:56:32 |

US3252127

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:09:59

[Was the pregnancy test performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'No (N)' | Shannon Moyer (b) (4) | 12 Aug 2020 19:27:58 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:09:59

Date of test (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Aug 2020 19:27:58 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:09:59

[Test performed](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Aug 2020 19:27:58 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:09:59

[Result](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Aug 2020 19:27:58 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:09:59

[Was FSH sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'No (N)' | Shannon Moyer (b) (4) | 12 Aug 2020 19:27:58 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:09:59

[Collection date](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Aug 2020 19:27:58 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:09:59

[Collection time](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Aug 2020 19:27:58 |
| | (b) (4) | |

US3252127

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:09:59

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User entered empty. | System | 12 Aug 2020 19:27:58 |

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:59

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 12 Aug 2020 19:30:33 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 12 Aug 2020 19:30:33 |
| User entered 'No (N)' reason for change: Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:30:33 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 12 Aug 2020 19:17:59 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:17:59 |

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:59

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 12 Aug 2020 19:30:33 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 12 Aug 2020 19:30:33 |
| User entered 'No (N)' reason for change: Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:30:33 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 12 Aug 2020 19:17:59 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:17:59 |

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:59

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 12 Aug 2020 19:30:33 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 12 Aug 2020 19:30:33 |
| User entered 'No (N)' reason for change: Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:30:33 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 12 Aug 2020 19:17:59 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:17:59 |

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:59

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 12 Aug 2020 19:30:33 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 12 Aug 2020 19:30:33 |
| User entered 'No (N)' reason for change: Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:30:33 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 12 Aug 2020 19:17:59 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:17:59 |

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:59

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 12 Aug 2020 19:30:33 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 12 Aug 2020 19:30:33 |
| User entered 'No (N)' reason for change: Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:30:33 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 12 Aug 2020 19:17:59 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:17:59 |

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:59

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 12 Aug 2020 19:30:33 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 12 Aug 2020 19:30:33 |
| User entered 'No (N)' reason for change: Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:30:33 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 12 Aug 2020 19:17:59 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:17:59 |

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:59

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 12 Aug 2020 19:30:33 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 12 Aug 2020 19:30:33 |
| User entered 'No (N)' reason for change: Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:30:33 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 12 Aug 2020 19:17:59 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:17:59 |

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:59

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 12 Aug 2020 19:30:33 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 12 Aug 2020 19:30:33 |
| User entered 'No (N)' reason for change: Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:30:33 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 12 Aug 2020 19:17:59 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:17:59 |

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:59

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 12 Aug 2020 19:30:33 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 12 Aug 2020 19:30:33 |
| User entered 'No (N)' reason for change: Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:30:33 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 12 Aug 2020 19:17:59 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:17:59 |

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:59

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 12 Aug 2020 19:30:33 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 12 Aug 2020 19:30:33 |
| User entered 'No (N)' reason for change: Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:30:33 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 12 Aug 2020 19:17:59 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:17:59 |

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:59

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 12 Aug 2020 19:30:33 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 12 Aug 2020 19:30:33 |
| User entered 'No (N)' reason for change: Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:30:33 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 12 Aug 2020 19:17:59 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:17:59 |

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:59

Other

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:17:59 |

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:59

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Retired' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:17:59 |

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:59

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:17:59 |

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:59

Resides in Nursing Home or Assisted Living Facility

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:17:59 |

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:59

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:17:59 |

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:59

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:17:59 |

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:59

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'I' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:17:59 |

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:59

[Resides in a single family home](#) (i.e., detached housing)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:17:59 |

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:59

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:17:59 |

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:59

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:34:11 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:17:59 |

US3252127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:24:22 |
| | (b) (4) | |

US3252127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '11 Aug 2020' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:24:22 |
| | (b) (4) | |

US3252127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Clinic (Clinic)' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:24:22 |
| | (b) (4) | |

US3252127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'VISIT1' | System | 11 Aug 2020 22:24:22 |

US3252127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:59

What was the date of randomization? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '11 AUG 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 11 Aug 2020 22:04:08 |

US3252127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:59

What was the participant's randomization number?

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 21 Aug 2020 03:43:40 |
| Amendment Manager: Data point set to conformant. | System | 21 Aug 2020 03:43:40 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 11 Aug 2020 22:04:08 |
| User entered '185790' (non-conformant). | RWS_ENDPOINT ENDPOINT (b) (4) | 11 Aug 2020 22:04:08 |

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:59

[In what Cohort was the participant enrolled?](#)

| Audit | User | Time (GMT) |
|-------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '>=65 years (3)' | RWS_ENDPOINT ENDPOINT (b) (4) | 11 Aug 2020 22:04:08 |

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:59

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:25:06 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:59

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:25:06 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:59

Severe obesity (body mass index > or = 40kg/m2

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'No (N)' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:25:06 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:59

Diabetes (Type I, Type 2, or gestational)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'No (N)' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:25:06 |
| | (b) (4) | |

US3252127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:59

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'No (N)' | Uche Ehiemua (b) (4) | 11 Aug 2020 22:25:06 |
| | (b) (4) | |

US3252127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:59

[Human Immunodeficiency Virus \(HIV\) infection](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'No (N)' | Nancy Torrence (b) (4) | 30 Sep 2020 05:05:23 |
| | (b) (4) | |
| Amendment Manager: DataPoint set to visible. | System | 19 Sep 2020 10:18:06 |
| Amendment Manager inserted this DataPoint. | System | 19 Sep 2020 06:38:33 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:59

Height

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 24 Aug 2020 18:28:40 |
| User entered empty; reason for change Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:20:20 |
| User entered '68.7' in | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:59

Weight

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 24 Aug 2020 18:28:40 |
| User entered empty; reason for change Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:20:20 |
| User entered '199' lb | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:59

Height

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 24 Aug 2020 18:28:40 |
| User entered empty; reason for change Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:20:20 |
| User entered '68.7' in | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:59

Weight

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 24 Aug 2020 18:28:40 |
| User entered empty; reason for change Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:20:20 |
| User entered '199' lb | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Joanna Gurrola Mahoney | 12 Aug 2020 19:42:03 |
| | (b) (4) | |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '11 Aug 2020' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '16:04' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered '11 Aug 2020 16:04' | System | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 20 Aug 2020 19:20:20 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 20 Aug 2020 19:20:20 |
| User entered '98.1' F reason for change: Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:20:20 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 12 Aug 2020 19:42:03 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 20 Aug 2020 19:20:20 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | Shannon Moyer (b) (4) (b) (4) | 20 Aug 2020 19:20:20 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 12 Aug 2020 19:42:03 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 20 Aug 2020 19:20:20 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 20 Aug 2020 19:20:20 |
| User entered '75' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:20:20 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 12 Aug 2020 19:42:03 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'bpm' | System | 20 Aug 2020 19:20:20 |
| User entered empty. | System | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 20 Aug 2020 19:20:20 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 20 Aug 2020 19:20:20 |
| User entered '15' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:20:20 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 12 Aug 2020 19:42:03 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'breaths/min' | System | 20 Aug 2020 19:20:20 |
| User entered empty. | System | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 20 Aug 2020 19:20:20 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 20 Aug 2020 19:20:20 |
| User entered '143' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:20:20 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 12 Aug 2020 19:42:03 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'mmHg' | System | 20 Aug 2020 19:20:20 |
| User entered empty. | System | 12 Aug 2020 19:42:03 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 20 Aug 2020 19:20:20 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 20 Aug 2020 19:20:20 |
| User entered '73' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:20:20 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 12 Aug 2020 19:42:03 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'mmHg' | System | 20 Aug 2020 19:20:20 |
| User entered empty. | System | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:59

Height

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 24 Aug 2020 18:28:40 |
| User entered empty; reason for change Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:20:20 |
| User entered '68.7' in | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:59

Weight

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 24 Aug 2020 18:28:40 |
| User entered empty; reason for change Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:20:20 |
| User entered '199' lb | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 20 Aug 2020 19:20:20 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 20 Aug 2020 19:20:20 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:20:20 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 12 Aug 2020 19:42:03 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '11 Aug 2020' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:20:20 |
| User entered empty. | (b) (4) | |
| | Joanna Gurrola Mahoney | 12 Aug 2020 19:42:03 |
| | (b) (4) | |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version. | | 21 Aug 2020 03:43:36 |
| Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per Source, correct as is' (Site from System). | Shannon Moyer (b) (4) | 20 Aug 2020 19:20:41 |
| User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System). | | 20 Aug 2020 19:20:20 |
| User entered '18:24' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:20:20 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered '11 Aug 2020 18:24' | System | 20 Aug 2020 19:20:20 |
| User entered empty. | System | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Per CDM: As per CCG, Data is required, please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 11 Nov 2020 15:36:37 |
| Query 'Per CDM: As per CCG, Data is required, please update accordingly.' answered with 'updated' (Site from DM). | Joanna Gurrola Mahoney (b) (4) | 09 Oct 2020 19:22:18 |
| User entered '97.5' F reason for change: Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 09 Oct 2020 19:20:01 |
| User opened query 'Per CDM: As per CCG, Data is required, please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 08 Oct 2020 14:56:19 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 24 Aug 2020 18:35:14 |
| User entered '97.5' F reason for change: Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:20:20 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 09 Oct 2020 19:20:01 |
| User entered empty; reason for change Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 24 Aug 2020 18:35:14 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:20:20 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Per CDM: As per CCG, Data is required, please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 11 Nov 2020 15:36:41 |
| Query 'Per CDM: As per CCG, Data is required, please update accordingly.' answered with 'updated' (Site from DM). | Joanna Gurrola Mahoney (b) (4) | 09 Oct 2020 19:22:20 |
| User entered '75' reason for change: Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 09 Oct 2020 19:20:01 |
| User opened query 'Per CDM: As per CCG, Data is required, please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 08 Oct 2020 14:56:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 24 Aug 2020 18:35:14 |
| User entered '75' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:20:20 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'bpm' | System | 20 Aug 2020 19:20:20 |
| User entered empty. | System | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Per CDM: As per CCG, Data is required, please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 11 Nov 2020 15:36:46 |
| Query 'Per CDM: As per CCG, Data is required, please update accordingly.' answered with 'updated' (Site from DM). | Joanna Gurrola Mahoney (b) (4) | 09 Oct 2020 19:22:34 |
| User entered '16' reason for change: Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 09 Oct 2020 19:20:01 |
| User opened query 'Per CDM: As per CCG, Data is required, please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 08 Oct 2020 14:56:30 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 24 Aug 2020 18:35:14 |
| User entered '16' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:20:20 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'breaths/min' | System | 20 Aug 2020 19:20:20 |
| User entered empty. | System | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Per CDM: As per CCG, Data is required, please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 11 Nov 2020 15:36:53 |
| Query 'Per CDM: As per CCG, Data is required, please update accordingly.' answered with 'updated' (Site from DM). | Joanna Gurrola Mahoney (b) (4) | 09 Oct 2020 19:22:41 |
| User entered '155' reason for change: Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 09 Oct 2020 19:20:01 |
| User opened query 'Per CDM: As per CCG, Data is required, please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 08 Oct 2020 14:56:36 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 24 Aug 2020 18:35:14 |
| User entered '155' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:20:20 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'mmHg' | System | 20 Aug 2020 19:20:20 |
| User entered empty. | System | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Per CDM: As per CCG, Data is required, please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 11 Nov 2020 15:36:57 |
| Query 'Per CDM: As per CCG, Data is required, please update accordingly.' answered with 'updated' (Site from DM). | Joanna Gurrola Mahoney (b) (4) | 09 Oct 2020 19:22:54 |
| User entered '75' reason for change: Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 09 Oct 2020 19:20:01 |
| User opened query 'Per CDM: As per CCG, Data is required, please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 08 Oct 2020 14:56:41 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 24 Aug 2020 18:35:14 |
| User entered '75' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:20:20 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'mmHg' | System | 20 Aug 2020 19:20:20 |
| User entered empty. | System | 12 Aug 2020 19:42:03 |

US3252127

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:59

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'No (N)' reason for change: Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 24 Aug 2020 18:27:31 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:43:10 |

US3252127

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:59

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty; reason for change Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 24 Aug 2020 18:27:31 |
| User entered '11 Aug 2020' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:43:10 |

US3252127

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:09:59

[Was the pregnancy test performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'No (N)' | Shannon Moyer (b) (4) | 20 Aug 2020 19:22:51 |
| | (b) (4) | |

US3252127

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:09:59

Date of test (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Shannon Moyer (b) (4) | 20 Aug 2020 19:22:51 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:09:59

[Test performed](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Shannon Moyer (b) (4) | 20 Aug 2020 19:22:51 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:09:59

[Result](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Shannon Moyer (b) (4) | 20 Aug 2020 19:22:51 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:09:59

[Was FSH sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Shannon Moyer (b) (4) | 20 Aug 2020 19:22:51 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:09:59

[Collection date](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Shannon Moyer (b) (4) | 20 Aug 2020 19:22:51 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:09:59

[Collection time](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Shannon Moyer (b) (4) | 20 Aug 2020 19:22:51 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:09:59

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User entered empty. | System | 20 Aug 2020 19:22:51 |

US3252127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:59

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Uche Ehiemua (b) (4) | 11 Aug 2020 23:07:38 |
| | (b) (4) | |

US3252127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:59

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Uche Ehiemua (b) (4) | 11 Aug 2020 23:07:38 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:59

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Uche Ehiemua (b) (4) | 11 Aug 2020 23:07:38 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:59

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 11 Aug 2020 23:07:38 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:59

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '11 Aug 2020' | Uche Ehiemua (b) (4) | 11 Aug 2020 23:07:38 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:59

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '17:34' | Uche Ehiemua (b) (4) | 11 Aug 2020 23:07:38 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:59

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User entered '11 Aug 2020 17:34' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:59

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Left Arm (LEFT ARM)' | Uche Ehiemua (b) (4) | 11 Aug 2020 23:07:38 |
| | (b) (4) | |

US3252127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:59

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User entered 'ONCE' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:59

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User entered 'INTRAMUSCULAR' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:59

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney | 12 Aug 2020 19:47:08 |
| | (b) (4) | |

US3252127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:59

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '11 Aug 2020' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:47:08 |

US3252127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:59

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '17:16' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:47:08 |

US3252127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:59

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User entered '11 Aug 2020 17:16' | System | 12 Aug 2020 19:47:08 |

US3252127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:09:59

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '11 Aug 2020' | Joanna Gurrola Mahoney | 12 Aug 2020 19:50:06 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:09:59

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:50:06 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:09:59

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:50:06 |

US3252127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:09:59

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '17:00' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:50:06 |

US3252127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:09:59

Collection date and time (derived)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User entered '11 Aug 2020 17:00' | System | 12 Aug 2020 19:50:06 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:09:59

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:50:06 |

US3252127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:09:59

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:50:06 |

US3252127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:09:59

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:50:06 |

US3252127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:09:59

Collection date and time (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User entered empty. | System | 12 Aug 2020 19:50:06 |

US3252127

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney | 12 Aug 2020 19:50:42 |
| | (b) (4) | |

US3252127

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User entered 'I' | System | 12 Aug 2020 19:50:42 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:25:40', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'be6f3f51-86ba-4bb6-8016-8210ddc707b1' | System | 11 Aug 2020 23:27:05 |
| User entered 'Yes (Y)' | System | 11 Aug 2020 23:27:05 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:25:59', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'be6f3f51-86ba-4bb6-8016-8210ddc707b1' | System | 11 Aug 2020 23:27:05 |
| User entered '97.5' | System | 11 Aug 2020 23:27:05 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:26:08', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'be6f3f51-86ba-4bb6-8016-8210ddc707b1' | System | 11 Aug 2020 23:27:05 |
| User entered 'No (N)' | System | 11 Aug 2020 23:27:05 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:27:02', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'be6f3f51-86ba-4bb6-8016-8210ddc707b1' | System | 11 Aug 2020 23:27:05 |
| User entered '11 Aug 2020 18:27' | System | 11 Aug 2020 23:27:05 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '11 Aug 2020 17:54' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '11 Aug 2020 20:24' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 1, after vaccination (at home)' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:41:23', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '6098d168-6c79-4ca0-9575-f78579489f49' | System | 12 Aug 2020 16:41:49 |
| User entered 'Yes (Y)' | System | 12 Aug 2020 16:41:49 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:41:31', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '6098d168-6c79-4ca0-9575-f78579489f49' | System | 12 Aug 2020 16:41:49 |
| User entered '97.3' | System | 12 Aug 2020 16:41:49 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:41:36', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '6098d168-6c79-4ca0-9575-f78579489f49' | System | 12 Aug 2020 16:41:49 |
| User entered 'No (N)' | System | 12 Aug 2020 16:41:49 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:41:49', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '6098d168-6c79-4ca0-9575-f78579489f49' | System | 12 Aug 2020 16:41:49 |
| User entered '12 Aug 2020 11:41' | System | 12 Aug 2020 16:41:49 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '11 Aug 2020 21:19' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '12 Aug 2020 11:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 2' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:17:25', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '10abd98d-b5fd-47b2-b028-85142d0e7e82' | System | 13 Aug 2020 05:17:52 |
| User entered 'Yes (Y)' | System | 13 Aug 2020 05:17:52 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:17:34', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '10abd98d-b5fd-47b2-b028-85142d0e7e82' | System | 13 Aug 2020 05:17:52 |
| User entered '97.3' | System | 13 Aug 2020 05:17:52 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:59

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:17:38', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '10abd98d-b5fd-47b2-b028-85142d0e7e82' | System | 13 Aug 2020 05:17:52 |
| User entered 'No (N)' | System | 13 Aug 2020 05:17:52 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:17:52', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '10abd98d-b5fd-47b2-b028-85142d0e7e82' | System | 13 Aug 2020 05:17:52 |
| User entered '13 Aug 2020 00:17' | System | 13 Aug 2020 05:17:52 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '12 Aug 2020 12:00' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '13 Aug 2020 11:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 3' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:33:45', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '06186ffc-fd9d-411e-b35a-a028cec19954' | System | 14 Aug 2020 00:34:04 |
| User entered 'Yes (Y)' | System | 14 Aug 2020 00:34:04 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:33:52', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '06186ffc-fd9d-411e-b35a-a028cec19954' | System | 14 Aug 2020 00:34:04 |
| User entered '96.6' | System | 14 Aug 2020 00:34:04 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:59

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:33:56', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '06186ffc-fd9d-411e-b35a-a028cec19954' | System | 14 Aug 2020 00:34:04 |
| User entered 'No (N)' | System | 14 Aug 2020 00:34:04 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:34:04', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '06186ffc-fd9d-411e-b35a-a028cec19954' | System | 14 Aug 2020 00:34:04 |
| User entered '13 Aug 2020 19:34' | System | 14 Aug 2020 00:34:04 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '13 Aug 2020 12:00' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '14 Aug 2020 11:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 4' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:03:18', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '014a9655-b936-41f6-a16b-7fd61bee4c73' | System | 15 Aug 2020 01:04:12 |
| User entered 'Yes (Y)' | System | 15 Aug 2020 01:04:12 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:03:40', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '014a9655-b936-41f6-a16b-7fd61bee4c73' | System | 15 Aug 2020 01:04:12 |
| User entered '97.9' | System | 15 Aug 2020 01:04:12 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:59

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:03:45', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '014a9655-b936-41f6-a16b-7fd61bee4c73' | System | 15 Aug 2020 01:04:12 |
| User entered 'No (N)' | System | 15 Aug 2020 01:04:12 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:04:14', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '014a9655-b936-41f6-a16b-7fd61bee4c73' | System | 15 Aug 2020 01:04:12 |
| User entered '14 Aug 2020 20:04' | System | 15 Aug 2020 01:04:12 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '14 Aug 2020 12:00' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '15 Aug 2020 11:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 5' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:29:57', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '940cb0bd-a927-46b8-9b26-8937487bd1be' | System | 16 Aug 2020 04:30:31 |
| User entered 'Yes (Y)' | System | 16 Aug 2020 04:30:31 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:30:14', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '940cb0bd-a927-46b8-9b26-8937487bd1be' | System | 16 Aug 2020 04:30:31 |
| User entered '97.6' | System | 16 Aug 2020 04:30:31 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:59

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:30:18', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '940cb0bd-a927-46b8-9b26-8937487bd1be' | System | 16 Aug 2020 04:30:31 |
| User entered 'No (N)' | System | 16 Aug 2020 04:30:31 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:30:30', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '940cb0bd-a927-46b8-9b26-8937487bd1be' | System | 16 Aug 2020 04:30:31 |
| User entered '15 Aug 2020 23:30' | System | 16 Aug 2020 04:30:31 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '15 Aug 2020 12:00' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '16 Aug 2020 11:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 6' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:08:11', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4a9360fc-5dc9-4477-95cb-31f5dc9a27b5' | System | 17 Aug 2020 03:08:36 |
| User entered 'Yes (Y)' | System | 17 Aug 2020 03:08:36 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:08:18', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4a9360fc-5dc9-4477-95cb-31f5dc9a27b5' | System | 17 Aug 2020 03:08:36 |
| User entered '97.6' | System | 17 Aug 2020 03:08:36 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:59

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:08:24', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4a9360fc-5dc9-4477-95cb-31f5dc9a27b5' | System | 17 Aug 2020 03:08:36 |
| User entered 'No (N)' | System | 17 Aug 2020 03:08:36 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:08:34', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4a9360fc-5dc9-4477-95cb-31f5dc9a27b5' | System | 17 Aug 2020 03:08:36 |
| User entered '16 Aug 2020 22:08' | System | 17 Aug 2020 03:08:36 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '16 Aug 2020 12:00' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '17 Aug 2020 11:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 7' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:56:39', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7f161c37-26f5-487b-968e-7e8e451f68ce' | System | 18 Aug 2020 00:57:02 |
| User entered 'Yes (Y)' | System | 18 Aug 2020 00:57:02 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:56:47', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7f161c37-26f5-487b-968e-7e8e451f68ce' | System | 18 Aug 2020 00:57:02 |
| User entered '97.7' | System | 18 Aug 2020 00:57:02 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:59

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:56:53', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7f161c37-26f5-487b-968e-7e8e451f68ce' | System | 18 Aug 2020 00:57:02 |
| User entered 'No (N)' | System | 18 Aug 2020 00:57:02 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:57:01', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7f161c37-26f5-487b-968e-7e8e451f68ce' | System | 18 Aug 2020 00:57:02 |
| User entered '17 Aug 2020 19:57' | System | 18 Aug 2020 00:57:02 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '17 Aug 2020 12:00' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '18 Aug 2020 11:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:35:07', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '88e7a31c-30c6-4397-8b97-d1174058c9eb' | System | 11 Aug 2020 23:35:23 |
| User entered 'None (1)' | System | 11 Aug 2020 23:35:23 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:35:09', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '88e7a31c-30c6-4397-8b97-d1174058c9eb' | System | 11 Aug 2020 23:35:23 |
| User entered 'No (N)' | System | 11 Aug 2020 23:35:23 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:35:12', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '88e7a31c-30c6-4397-8b97-d1174058c9eb' | System | 11 Aug 2020 23:35:23 |
| User entered 'No (N)' | System | 11 Aug 2020 23:35:23 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:35:15', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '88e7a31c-30c6-4397-8b97-d1174058c9eb' | System | 11 Aug 2020 23:35:23 |
| User entered 'None (1)' | System | 11 Aug 2020 23:35:23 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:35:21', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '88e7a31c-30c6-4397-8b97-d1174058c9eb' | System | 11 Aug 2020 23:35:23 |
| User entered '11 Aug 2020 18:35' | System | 11 Aug 2020 23:35:23 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '11 Aug 2020 17:54' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '11 Aug 2020 20:24' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 1, after vaccination (at home)' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:42:35', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'ce7efdd1-1149-4de5-a2ee-3309647a4ea8' | System | 12 Aug 2020 16:43:54 |
| User entered 'Does not interfere with activity (2)' | System | 12 Aug 2020 16:43:54 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:43:13', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'ce7efdd1-1149-4de5-a2ee-3309647a4ea8' | System | 12 Aug 2020 16:43:54 |
| User entered 'No (N)' | System | 12 Aug 2020 16:43:54 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:43:18', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'ce7efdd1-1149-4de5-a2ee-3309647a4ea8' | System | 12 Aug 2020 16:43:54 |
| User entered 'No (N)' | System | 12 Aug 2020 16:43:54 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:43:23', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'ce7efdd1-1149-4de5-a2ee-3309647a4ea8' | System | 12 Aug 2020 16:43:54 |
| User entered 'None (1)' | System | 12 Aug 2020 16:43:54 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:43:34', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'ce7efdd1-1149-4de5-a2ee-3309647a4ea8' | System | 12 Aug 2020 16:43:54 |
| User entered '12 Aug 2020 11:43' | System | 12 Aug 2020 16:43:54 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '11 Aug 2020 21:19' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '12 Aug 2020 11:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 2' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:18:14', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4f03cc91-9698-4428-ae75-872d08be38a4' | System | 13 Aug 2020 05:18:54 |
| User entered 'Does not interfere with activity (2)' | System | 13 Aug 2020 05:18:54 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:59

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:18:18', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4f03cc91-9698-4428-ae75-872d08be38a4' | System | 13 Aug 2020 05:18:54 |
| User entered 'No (N)' | System | 13 Aug 2020 05:18:54 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:18:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4f03cc91-9698-4428-ae75-872d08be38a4' | System | 13 Aug 2020 05:18:54 |
| User entered 'No (N)' | System | 13 Aug 2020 05:18:54 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:18:43', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4f03cc91-9698-4428-ae75-872d08be38a4' | System | 13 Aug 2020 05:18:54 |
| User entered 'None (1)' | System | 13 Aug 2020 05:18:54 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:18:51', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4f03cc91-9698-4428-ae75-872d08be38a4' | System | 13 Aug 2020 05:18:54 |
| User entered '13 Aug 2020 00:18' | System | 13 Aug 2020 05:18:54 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '12 Aug 2020 12:00' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '13 Aug 2020 11:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 3' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:34:19', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3ae99b12-236c-40f5-b596-95c1c562d4ed' | System | 14 Aug 2020 00:34:42 |
| User entered 'Does not interfere with activity (2)' | System | 14 Aug 2020 00:34:42 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:59

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:34:22', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3ae99b12-236c-40f5-b596-95c1c562d4ed' | System | 14 Aug 2020 00:34:42 |
| User entered 'No (N)' | System | 14 Aug 2020 00:34:42 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:34:26', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3ae99b12-236c-40f5-b596-95c1c562d4ed' | System | 14 Aug 2020 00:34:42 |
| User entered 'No (N)' | System | 14 Aug 2020 00:34:42 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:34:31', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3ae99b12-236c-40f5-b596-95c1c562d4ed' | System | 14 Aug 2020 00:34:42 |
| User entered 'None (1)' | System | 14 Aug 2020 00:34:42 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:34:43', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3ae99b12-236c-40f5-b596-95c1c562d4ed' | System | 14 Aug 2020 00:34:42 |
| User entered '13 Aug 2020 19:34' | System | 14 Aug 2020 00:34:42 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '13 Aug 2020 12:00' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '14 Aug 2020 11:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 4' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:04:35', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2cca1f2e-84f8-4538-bd12-8c07d152637e' | System | 15 Aug 2020 01:05:04 |
| User entered 'None (1)' | System | 15 Aug 2020 01:05:04 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:59

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:04:39', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2cca1f2e-84f8-4538-bd12-8c07d152637e' | System | 15 Aug 2020 01:05:04 |
| User entered 'No (N)' | System | 15 Aug 2020 01:05:04 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:04:42', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2cca1f2e-84f8-4538-bd12-8c07d152637e' | System | 15 Aug 2020 01:05:04 |
| User entered 'No (N)' | System | 15 Aug 2020 01:05:04 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:04:54', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2cca1f2e-84f8-4538-bd12-8c07d152637e' | System | 15 Aug 2020 01:05:04 |
| User entered 'None (1)' | System | 15 Aug 2020 01:05:04 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:05:02', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2cca1f2e-84f8-4538-bd12-8c07d152637e' | System | 15 Aug 2020 01:05:04 |
| User entered '14 Aug 2020 20:05' | System | 15 Aug 2020 01:05:04 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '14 Aug 2020 12:00' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '15 Aug 2020 11:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 5' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:30:41', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3d292382-ae6d-4214-b9d4-ec43f6ae0d41' | System | 16 Aug 2020 04:31:08 |
| User entered 'None (1)' | System | 16 Aug 2020 04:31:08 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:59

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:30:44', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3d292382-ae6d-4214-b9d4-ec43f6ae0d41' | System | 16 Aug 2020 04:31:08 |
| User entered 'No (N)' | System | 16 Aug 2020 04:31:08 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:30:48', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3d292382-ae6d-4214-b9d4-ec43f6ae0d41' | System | 16 Aug 2020 04:31:08 |
| User entered 'No (N)' | System | 16 Aug 2020 04:31:08 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:30:56', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3d292382-ae6d-4214-b9d4-ec43f6ae0d41' | System | 16 Aug 2020 04:31:08 |
| User entered 'None (1)' | System | 16 Aug 2020 04:31:08 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:31:04', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3d292382-ae6d-4214-b9d4-ec43f6ae0d41' | System | 16 Aug 2020 04:31:08 |
| User entered '15 Aug 2020 23:31' | System | 16 Aug 2020 04:31:08 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '15 Aug 2020 12:00' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '16 Aug 2020 11:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 6' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:08:55', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2ce74553-d4b1-46c4-9842-a8c456a18a5e' | System | 17 Aug 2020 03:09:18 |
| User entered 'None (1)' | System | 17 Aug 2020 03:09:18 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:59

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:08:59', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2ce74553-d4b1-46c4-9842-a8c456a18a5e' | System | 17 Aug 2020 03:09:18 |
| User entered 'No (N)' | System | 17 Aug 2020 03:09:18 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:09:02', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2ce74553-d4b1-46c4-9842-a8c456a18a5e' | System | 17 Aug 2020 03:09:18 |
| User entered 'No (N)' | System | 17 Aug 2020 03:09:18 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:09:05', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2ce74553-d4b1-46c4-9842-a8c456a18a5e' | System | 17 Aug 2020 03:09:18 |
| User entered 'None (1)' | System | 17 Aug 2020 03:09:18 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:09:16', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2ce74553-d4b1-46c4-9842-a8c456a18a5e' | System | 17 Aug 2020 03:09:18 |
| User entered '16 Aug 2020 22:09' | System | 17 Aug 2020 03:09:18 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '16 Aug 2020 12:00' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '17 Aug 2020 11:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 7' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:58:02', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '152478a4-5aa5-4c9d-bbf2-b739cf05f6ce' | System | 18 Aug 2020 00:58:23 |
| User entered 'None (1)' | System | 18 Aug 2020 00:58:23 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:59

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:58:05', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '152478a4-5aa5-4c9d-bbf2-b739cf05f6ce' | System | 18 Aug 2020 00:58:23 |
| User entered 'No (N)' | System | 18 Aug 2020 00:58:23 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:58:10', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '152478a4-5aa5-4c9d-bbf2-b739cf05f6ce' | System | 18 Aug 2020 00:58:23 |
| User entered 'No (N)' | System | 18 Aug 2020 00:58:23 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:58:16', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '152478a4-5aa5-4c9d-bbf2-b739cf05f6ce' | System | 18 Aug 2020 00:58:23 |
| User entered 'None (1)' | System | 18 Aug 2020 00:58:23 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:58:25', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '152478a4-5aa5-4c9d-bbf2-b739cf05f6ce' | System | 18 Aug 2020 00:58:23 |
| User entered '17 Aug 2020 19:58' | System | 18 Aug 2020 00:58:23 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '17 Aug 2020 12:00' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '18 Aug 2020 11:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:35:25', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'acdf26f4-0624-4fb9-8041-b0eb6974e24e' | System | 11 Aug 2020 23:35:48 |
| User entered 'None (0)' | System | 11 Aug 2020 23:35:48 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:35:28', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'acdf26f4-0624-4fb9-8041-b0eb6974e24e' | System | 11 Aug 2020 23:35:48 |
| User entered 'None (0)' | System | 11 Aug 2020 23:35:48 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:35:29', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'acdf26f4-0624-4fb9-8041-b0eb6974e24e' | System | 11 Aug 2020 23:35:48 |
| User entered 'None (0)' | System | 11 Aug 2020 23:35:48 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:35:31', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'acdf26f4-0624-4fb9-8041-b0eb6974e24e' | System | 11 Aug 2020 23:35:48 |
| User entered 'None (0)' | System | 11 Aug 2020 23:35:48 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:35:34', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'acdf26f4-0624-4fb9-8041-b0eb6974e24e' | System | 11 Aug 2020 23:35:48 |
| User entered 'None (0)' | System | 11 Aug 2020 23:35:48 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:35:40', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'acdf26f4-0624-4fb9-8041-b0eb6974e24e' | System | 11 Aug 2020 23:35:48 |
| User entered 'None (0)' | System | 11 Aug 2020 23:35:48 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:35:43', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'acdf26f4-0624-4fb9-8041-b0eb6974e24e' | System | 11 Aug 2020 23:35:48 |
| User entered 'No (N)' | System | 11 Aug 2020 23:35:48 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:35:46', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'acdf26f4-0624-4fb9-8041-b0eb6974e24e' | System | 11 Aug 2020 23:35:48 |
| User entered '11 Aug 2020 18:35' | System | 11 Aug 2020 23:35:48 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '11 Aug 2020 17:54' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '11 Aug 2020 20:24' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 1, after vaccination (at home)' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:43:45', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7bbff10f-35d0-4209-b67a-84c38432b4e0' | System | 12 Aug 2020 16:44:55 |
| User entered 'None (0)' | System | 12 Aug 2020 16:44:55 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:43:50', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7bbff10f-35d0-4209-b67a-84c38432b4e0' | System | 12 Aug 2020 16:44:55 |
| User entered 'None (0)' | System | 12 Aug 2020 16:44:55 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:43:55', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7bbff10f-35d0-4209-b67a-84c38432b4e0' | System | 12 Aug 2020 16:44:55 |
| User entered 'None (0)' | System | 12 Aug 2020 16:44:55 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:44:00', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7bbff10f-35d0-4209-b67a-84c38432b4e0' | System | 12 Aug 2020 16:44:55 |
| User entered 'None (0)' | System | 12 Aug 2020 16:44:55 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:44:04', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7bbff10f-35d0-4209-b67a-84c38432b4e0' | System | 12 Aug 2020 16:44:55 |
| User entered 'None (0)' | System | 12 Aug 2020 16:44:55 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:44:08', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7bbff10f-35d0-4209-b67a-84c38432b4e0' | System | 12 Aug 2020 16:44:55 |
| User entered 'None (0)' | System | 12 Aug 2020 16:44:55 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:44:20', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7bbff10f-35d0-4209-b67a-84c38432b4e0' | System | 12 Aug 2020 16:44:55 |
| User entered 'No (N)' | System | 12 Aug 2020 16:44:55 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:44:40', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7bbff10f-35d0-4209-b67a-84c38432b4e0' | System | 12 Aug 2020 16:44:55 |
| User entered '12 Aug 2020 11:44' | System | 12 Aug 2020 16:44:55 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '11 Aug 2020 21:19' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '12 Aug 2020 11:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 2' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:18:57', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '9a2d332e-d6a4-4972-91d0-3b63b121cfc1' | System | 13 Aug 2020 05:19:49 |
| User entered 'None (0)' | System | 13 Aug 2020 05:19:49 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:19:02', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '9a2d332e-d6a4-4972-91d0-3b63b121cfc1' | System | 13 Aug 2020 05:19:49 |
| User entered 'None (0)' | System | 13 Aug 2020 05:19:49 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:19:08', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '9a2d332e-d6a4-4972-91d0-3b63b121cfc1' | System | 13 Aug 2020 05:19:49 |
| User entered 'None (0)' | System | 13 Aug 2020 05:19:49 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:19:13', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '9a2d332e-d6a4-4972-91d0-3b63b121cfc1' | System | 13 Aug 2020 05:19:49 |
| User entered 'None (0)' | System | 13 Aug 2020 05:19:49 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:19:17', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '9a2d332e-d6a4-4972-91d0-3b63b121cfc1' | System | 13 Aug 2020 05:19:49 |
| User entered 'None (0)' | System | 13 Aug 2020 05:19:49 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:19:23', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '9a2d332e-d6a4-4972-91d0-3b63b121cfc1' | System | 13 Aug 2020 05:19:49 |
| User entered 'None (0)' | System | 13 Aug 2020 05:19:49 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:19:36', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '9a2d332e-d6a4-4972-91d0-3b63b121cfc1' | System | 13 Aug 2020 05:19:49 |
| User entered 'No (N)' | System | 13 Aug 2020 05:19:49 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:19:46', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '9a2d332e-d6a4-4972-91d0-3b63b121cfc1' | System | 13 Aug 2020 05:19:49 |
| User entered '13 Aug 2020 00:19' | System | 13 Aug 2020 05:19:49 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '12 Aug 2020 12:00' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '13 Aug 2020 11:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 3' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:34:55', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '98c82b4b-7648-4f30-938c-ba8c826adabd' | System | 14 Aug 2020 00:36:04 |
| User entered 'None (0)' | System | 14 Aug 2020 00:36:04 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:35:19', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '98c82b4b-7648-4f30-938c-ba8c826adabd' | System | 14 Aug 2020 00:36:04 |
| User entered 'None (0)' | System | 14 Aug 2020 00:36:04 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:35:25', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '98c82b4b-7648-4f30-938c-ba8c826adabd' | System | 14 Aug 2020 00:36:04 |
| User entered 'None (0)' | System | 14 Aug 2020 00:36:04 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:35:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '98c82b4b-7648-4f30-938c-ba8c826adabd' | System | 14 Aug 2020 00:36:04 |
| User entered 'None (0)' | System | 14 Aug 2020 00:36:04 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:35:40', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '98c82b4b-7648-4f30-938c-ba8c826adabd' | System | 14 Aug 2020 00:36:04 |
| User entered 'None (0)' | System | 14 Aug 2020 00:36:04 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:35:47', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '98c82b4b-7648-4f30-938c-ba8c826adabd' | System | 14 Aug 2020 00:36:04 |
| User entered 'None (0)' | System | 14 Aug 2020 00:36:04 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:35:55', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '98c82b4b-7648-4f30-938c-ba8c826adabd' | System | 14 Aug 2020 00:36:04 |
| User entered 'No (N)' | System | 14 Aug 2020 00:36:04 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:36:04', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '98c82b4b-7648-4f30-938c-ba8c826adabd' | System | 14 Aug 2020 00:36:04 |
| User entered '13 Aug 2020 19:36' | System | 14 Aug 2020 00:36:04 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '13 Aug 2020 12:00' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '14 Aug 2020 11:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 4' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:05:07', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '03b82527-5c42-4e6f-be26-4b00208311d7' | System | 15 Aug 2020 01:05:47 |
| User entered 'None (0)' | System | 15 Aug 2020 01:05:47 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:05:18', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '03b82527-5c42-4e6f-be26-4b00208311d7' | System | 15 Aug 2020 01:05:47 |
| User entered 'None (0)' | System | 15 Aug 2020 01:05:47 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:05:21', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '03b82527-5c42-4e6f-be26-4b00208311d7' | System | 15 Aug 2020 01:05:47 |
| User entered 'None (0)' | System | 15 Aug 2020 01:05:47 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:05:26', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '03b82527-5c42-4e6f-be26-4b00208311d7' | System | 15 Aug 2020 01:05:47 |
| User entered 'None (0)' | System | 15 Aug 2020 01:05:47 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:05:29', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '03b82527-5c42-4e6f-be26-4b00208311d7' | System | 15 Aug 2020 01:05:47 |
| User entered 'None (0)' | System | 15 Aug 2020 01:05:47 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:05:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '03b82527-5c42-4e6f-be26-4b00208311d7' | System | 15 Aug 2020 01:05:47 |
| User entered 'None (0)' | System | 15 Aug 2020 01:05:47 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:05:41', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '03b82527-5c42-4e6f-be26-4b00208311d7' | System | 15 Aug 2020 01:05:47 |
| User entered 'No (N)' | System | 15 Aug 2020 01:05:47 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:05:48', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '03b82527-5c42-4e6f-be26-4b00208311d7' | System | 15 Aug 2020 01:05:47 |
| User entered '14 Aug 2020 20:05' | System | 15 Aug 2020 01:05:47 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '14 Aug 2020 12:00' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '15 Aug 2020 11:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 5' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:31:10', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e9deb329-2b67-47a1-af7e-4f0c681e99b1' | System | 16 Aug 2020 04:32:01 |
| User entered 'None (0)' | System | 16 Aug 2020 04:32:01 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:31:18', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e9deb329-2b67-47a1-af7e-4f0c681e99b1' | System | 16 Aug 2020 04:32:01 |
| User entered 'None (0)' | System | 16 Aug 2020 04:32:01 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:31:23', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e9deb329-2b67-47a1-af7e-4f0c681e99b1' | System | 16 Aug 2020 04:32:01 |
| User entered 'None (0)' | System | 16 Aug 2020 04:32:01 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:31:31', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e9deb329-2b67-47a1-af7e-4f0c681e99b1' | System | 16 Aug 2020 04:32:01 |
| User entered 'None (0)' | System | 16 Aug 2020 04:32:01 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:31:34', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e9deb329-2b67-47a1-af7e-4f0c681e99b1' | System | 16 Aug 2020 04:32:01 |
| User entered 'None (0)' | System | 16 Aug 2020 04:32:01 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:31:37', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e9deb329-2b67-47a1-af7e-4f0c681e99b1' | System | 16 Aug 2020 04:32:01 |
| User entered 'None (0)' | System | 16 Aug 2020 04:32:01 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:31:47', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e9deb329-2b67-47a1-af7e-4f0c681e99b1' | System | 16 Aug 2020 04:32:01 |
| User entered 'No (N)' | System | 16 Aug 2020 04:32:01 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:31:59', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e9deb329-2b67-47a1-af7e-4f0c681e99b1' | System | 16 Aug 2020 04:32:01 |
| User entered '15 Aug 2020 23:31' | System | 16 Aug 2020 04:32:01 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '15 Aug 2020 12:00' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '16 Aug 2020 11:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 6' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:09:21', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b02b6d24-c179-4c44-a086-828fb899368f' | System | 17 Aug 2020 03:09:51 |
| User entered 'None (0)' | System | 17 Aug 2020 03:09:51 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:09:25', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b02b6d24-c179-4c44-a086-828fb899368f' | System | 17 Aug 2020 03:09:51 |
| User entered 'None (0)' | System | 17 Aug 2020 03:09:51 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:09:28', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b02b6d24-c179-4c44-a086-828fb899368f' | System | 17 Aug 2020 03:09:51 |
| User entered 'None (0)' | System | 17 Aug 2020 03:09:51 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:09:31', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b02b6d24-c179-4c44-a086-828fb899368f' | System | 17 Aug 2020 03:09:51 |
| User entered 'None (0)' | System | 17 Aug 2020 03:09:51 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:09:34', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b02b6d24-c179-4c44-a086-828fb899368f' | System | 17 Aug 2020 03:09:51 |
| User entered 'None (0)' | System | 17 Aug 2020 03:09:51 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:09:37', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b02b6d24-c179-4c44-a086-828fb899368f' | System | 17 Aug 2020 03:09:51 |
| User entered 'None (0)' | System | 17 Aug 2020 03:09:51 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:09:42', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b02b6d24-c179-4c44-a086-828fb899368f' | System | 17 Aug 2020 03:09:51 |
| User entered 'No (N)' | System | 17 Aug 2020 03:09:51 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:09:51', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b02b6d24-c179-4c44-a086-828fb899368f' | System | 17 Aug 2020 03:09:51 |
| User entered '16 Aug 2020 22:09' | System | 17 Aug 2020 03:09:51 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '16 Aug 2020 12:00' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '17 Aug 2020 11:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 7' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:58:35', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3463d7ce-828e-49cc-a634-96bfaef008ed' | System | 18 Aug 2020 00:59:19 |
| User entered 'None (0)' | System | 18 Aug 2020 00:59:19 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:58:39', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3463d7ce-828e-49cc-a634-96bfaef008ed' | System | 18 Aug 2020 00:59:19 |
| User entered 'None (0)' | System | 18 Aug 2020 00:59:19 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:58:42', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3463d7ce-828e-49cc-a634-96bfaef008ed' | System | 18 Aug 2020 00:59:19 |
| User entered 'None (0)' | System | 18 Aug 2020 00:59:19 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:58:46', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3463d7ce-828e-49cc-a634-96bfaef008ed' | System | 18 Aug 2020 00:59:19 |
| User entered 'None (0)' | System | 18 Aug 2020 00:59:19 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:58:49', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3463d7ce-828e-49cc-a634-96bfaef008ed' | System | 18 Aug 2020 00:59:19 |
| User entered 'None (0)' | System | 18 Aug 2020 00:59:19 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:58:53', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3463d7ce-828e-49cc-a634-96bfaef008ed' | System | 18 Aug 2020 00:59:19 |
| User entered 'None (0)' | System | 18 Aug 2020 00:59:19 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:59:08', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3463d7ce-828e-49cc-a634-96bfaef008ed' | System | 18 Aug 2020 00:59:19 |
| User entered 'No (N)' | System | 18 Aug 2020 00:59:19 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:59:20', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3463d7ce-828e-49cc-a634-96bfaef008ed' | System | 18 Aug 2020 00:59:19 |
| User entered '17 Aug 2020 19:59' | System | 18 Aug 2020 00:59:19 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '17 Aug 2020 12:00' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:33:19 |
| User entered '18 Aug 2020 11:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 20 Aug 2020 19:30:50 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '20 Aug 2020' | Shannon Moyer (b) (4) | 20 Aug 2020 19:30:50 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Contact Made (CONTACT MADE)' | Shannon Moyer (b) (4) | 20 Aug 2020 19:30:50 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Shannon Moyer (b) (4) | 20 Aug 2020 19:30:50 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 20 Aug 2020 19:31:09 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User entered 'I' | System | 20 Aug 2020 19:31:09 |

US3252127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 26 Aug 2020 16:26:07 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '25 Aug 2020' | Shannon Moyer (b) (4) | 26 Aug 2020 16:26:07 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Contact Made (CONTACT MADE)' | Shannon Moyer (b) (4) | 26 Aug 2020 16:26:07 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Shannon Moyer (b) (4) | 26 Aug 2020 16:26:07 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 26 Aug 2020 16:26:14 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User entered 'I' | System | 26 Aug 2020 16:26:14 |

US3252127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 02 Sep 2020 21:33:29 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '01 Sep 2020' | Shannon Moyer (b) (4) | 02 Sep 2020 21:33:29 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Contact Made (CONTACT MADE)' | Shannon Moyer (b) (4) | 02 Sep 2020 21:33:29 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Shannon Moyer (b) (4) | 02 Sep 2020 21:33:29 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 02 Sep 2020 21:33:34 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User entered 'I' | System | 02 Sep 2020 21:33:34 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 09 Sep 2020 02:55:33 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '8 Sep 2020' | Shannon Moyer (b) (4) | 09 Sep 2020 02:55:33 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Clinic (Clinic)' | Shannon Moyer (b) (4) | 09 Sep 2020 02:55:33 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'VISIT2' | System | 09 Sep 2020 02:55:33 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Shannon Moyer (b) (4) | 09 Sep 2020 02:58:44 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 09 Sep 2020 02:58:44 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '8 Sep 2020' | Shannon Moyer (b) (4) | 09 Sep 2020 02:58:44 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '15:39' | Shannon Moyer (b) (4) | 09 Sep 2020 02:58:44 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered '8 Sep 2020 15:39' | System | 09 Sep 2020 02:58:44 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '97.5' F | Shannon Moyer (b) (4) | 09 Sep 2020 02:58:44 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Oral (Oral)' | Shannon Moyer (b) (4) | 09 Sep 2020 02:58:44 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Shannon Moyer (b) (4) | 09 Sep 2020 02:58:44 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '74' | Shannon Moyer (b) (4) | 09 Sep 2020 02:58:44 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'bpm' | System | 09 Sep 2020 02:58:44 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '16' | Shannon Moyer (b) (4) | 09 Sep 2020 02:58:44 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'breaths/min' | System | 09 Sep 2020 02:58:44 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '120' | Shannon Moyer (b) (4) | 09 Sep 2020 02:58:44 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'mmHg' | System | 09 Sep 2020 02:58:44 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '67' | Shannon Moyer (b) (4) | 09 Sep 2020 02:58:44 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:59

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'mmHg' | System | 09 Sep 2020 02:58:44 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Shannon Moyer (b) (4) (b) (4) | 09 Sep 2020 02:58:44 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 09 Sep 2020 02:58:44 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '8 Sep 2020' | Shannon Moyer (b) (4) | 09 Sep 2020 02:58:44 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '16:41' | Shannon Moyer (b) (4) | 09 Sep 2020 02:58:44 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered '8 Sep 2020 16:41' | System | 09 Sep 2020 02:58:44 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '98.1' F | Shannon Moyer (b) (4) | 09 Sep 2020 02:58:44 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 09 Sep 2020 02:59:55 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 09 Sep 2020 02:59:55 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 09 Sep 2020 02:59:55 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | 09 Sep 2020 02:58:44 |
| User entered empty. | Shannon Moyer (b) (4) | 09 Sep 2020 02:58:44 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Shannon Moyer (b) (4) | 09 Sep 2020 02:58:44 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 09 Sep 2020 02:59:55 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 09 Sep 2020 02:59:55 |
| User entered '69' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 09 Sep 2020 02:59:55 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | 09 Sep 2020 02:58:44 |
| User entered empty. | Shannon Moyer (b) (4) | 09 Sep 2020 02:58:44 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'bpm' | System | 09 Sep 2020 02:59:55 |
| User entered empty. | System | 09 Sep 2020 02:58:44 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 09 Sep 2020 02:59:55 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 09 Sep 2020 02:59:55 |
| User entered '15' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 09 Sep 2020 02:59:55 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 09 Sep 2020 02:58:44 |
| User entered empty. | Shannon Moyer (b) (4) | 09 Sep 2020 02:58:44 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'breaths/min' | System | 09 Sep 2020 02:59:55 |
| User entered empty. | System | 09 Sep 2020 02:58:44 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 09 Sep 2020 02:59:55 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 09 Sep 2020 02:59:55 |
| User entered '128' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 09 Sep 2020 02:59:55 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 09 Sep 2020 02:58:44 |
| User entered empty. | Shannon Moyer (b) (4) | 09 Sep 2020 02:58:44 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'mmHg' | System | 09 Sep 2020 02:59:55 |
| User entered empty. | System | 09 Sep 2020 02:58:44 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 09 Sep 2020 02:59:55 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 09 Sep 2020 02:59:55 |
| User entered '66' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 09 Sep 2020 02:59:55 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | 09 Sep 2020 02:58:44 |
| User entered empty. | System | 09 Sep 2020 02:58:44 |
| | Shannon Moyer (b) (4) | 09 Sep 2020 02:58:44 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:59

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'mmHg' | System | 09 Sep 2020 02:59:55 |
| User entered empty. | System | 09 Sep 2020 02:58:44 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:59

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'No (N)' | Shannon Moyer (b) (4) | 09 Sep 2020 03:00:18 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:59

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Shannon Moyer (b) (4) | 09 Sep 2020 03:00:18 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:09:59

[Was the pregnancy test performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 09 Sep 2020 13:05:04 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:09:59

Date of test (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 09 Sep 2020 13:05:04 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:09:59

[Test performed](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 09 Sep 2020 13:05:04 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:09:59

[Result](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 09 Sep 2020 13:05:04 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:09:59

[Was FSH sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 09 Sep 2020 13:05:04 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:09:59

[Collection date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 09 Sep 2020 13:05:04 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:09:59

[Collection time](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 09 Sep 2020 13:05:04 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:09:59

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered empty. | System | 09 Sep 2020 13:05:04 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:59

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 09 Sep 2020 03:00:42 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 09 Sep 2020 03:00:42 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 09 Sep 2020 03:00:42 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 08 Sep 2020 21:18:21 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 08 Sep 2020 21:18:21 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:59

If No, reason not given

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 08 Sep 2020 21:18:21 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:59

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 08 Sep 2020 21:18:21 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:59

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 09 Sep 2020 03:00:42 |
| User entered empty. | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:59

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '8 Sep 2020' | Joanna Gurrola Mahoney (b) (4) | 08 Sep 2020 21:18:21 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:59

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '16:09' | Joanna Gurrola Mahoney (b) (4) | 08 Sep 2020 21:18:21 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:59

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered '8 Sep 2020 16:09' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:59

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Left Arm (LEFT ARM)' | Joanna Gurrola Mahoney | 08 Sep 2020 21:18:21 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:59

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'ONCE' | System | 09 Sep 2020 03:00:42 |
| User entered empty. | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:59

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'INTRAMUSCULAR' | System | 09 Sep 2020 03:00:42 |
| User entered empty. | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:59

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 09 Sep 2020 03:01:31 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:59

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '8 Sep 2020' | Shannon Moyer (b) (4) | 09 Sep 2020 03:01:31 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:59

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '16:06' | Shannon Moyer (b) (4) | 09 Sep 2020 03:01:31 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:59

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered '8 Sep 2020 16:06' | System | 09 Sep 2020 03:01:31 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:09:59

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '8 Sep 2020' | Shannon Moyer (b) (4) | 09 Sep 2020 03:02:31 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:09:59

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Shannon Moyer (b) (4) (b) (4) | 09 Sep 2020 03:02:31 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:09:59

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 09 Sep 2020 03:02:31 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:09:59

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '16:00' | Shannon Moyer (b) (4) | 09 Sep 2020 03:02:31 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:09:59

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered '8 Sep 2020 16:00' | System | 09 Sep 2020 03:02:31 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:09:59

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Shannon Moyer (b) (4) (b) (4) | 09 Sep 2020 03:02:31 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:09:59

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'No (N)' | Shannon Moyer (b) (4) | 09 Sep 2020 03:02:31 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:09:59

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Shannon Moyer (b) (4) | 09 Sep 2020 03:02:31 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:09:59

Collection date and time (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered empty. | System | 09 Sep 2020 03:02:31 |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 09 Sep 2020 03:02:39 |
| | (b) (4) | |

US3252127

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered '1' | System | 09 Sep 2020 03:02:39 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| Data entry locked. | System | 08 Sep 2020 21:18:21 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:44:26', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '24d1d5f7-632e-43ca-8732-f56945948d4a' | System | 08 Sep 2020 21:44:42 |
| User entered 'Yes (Y)' | System | 08 Sep 2020 21:44:42 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:44:32', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '24d1d5f7-632e-43ca-8732-f56945948d4a' | System | 08 Sep 2020 21:44:42 |
| User entered '98.1' | System | 08 Sep 2020 21:44:42 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:44:36', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '24d1d5f7-632e-43ca-8732-f56945948d4a' | System | 08 Sep 2020 21:44:42 |
| User entered 'No (N)' | System | 08 Sep 2020 21:44:42 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:44:41', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '24d1d5f7-632e-43ca-8732-f56945948d4a' | System | 08 Sep 2020 21:44:42 |
| User entered '08 Sep 2020 16:44' | System | 08 Sep 2020 21:44:42 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '08 Sep 2020 16:29' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '08 Sep 2020 18:59' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| Data entry locked. | System | 08 Sep 2020 21:18:21 |
| User entered 'Day 1, after vaccination (at home)' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:46:05', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'ba1520cd-e166-41e1-8115-025eef1e78a2' | System | 09 Sep 2020 05:47:05 |
| User entered 'Yes (Y)' | System | 09 Sep 2020 05:47:05 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:46:52', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'ba1520cd-e166-41e1-8115-025eef1e78a2' | System | 09 Sep 2020 05:47:05 |
| User entered '97.0' | System | 09 Sep 2020 05:47:05 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:46:56', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'ba1520cd-e166-41e1-8115-025eef1e78a2' | System | 09 Sep 2020 05:47:05 |
| User entered 'No (N)' | System | 09 Sep 2020 05:47:05 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:47:03', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'ba1520cd-e166-41e1-8115-025eef1e78a2' | System | 09 Sep 2020 05:47:05 |
| User entered '09 Sep 2020 00:47' | System | 09 Sep 2020 05:47:05 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '08 Sep 2020 19:54' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '09 Sep 2020 11:59' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| Data entry locked. | System | 08 Sep 2020 21:18:21 |
| User entered 'Day 2' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:57:36', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '05c2e67b-e572-4a51-9200-017c9bb253fb' | System | 10 Sep 2020 02:58:14 |
| User entered 'Yes (Y)' | System | 10 Sep 2020 02:58:14 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:57:46', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '05c2e67b-e572-4a51-9200-017c9bb253fb' User entered '98.9' | System | 10 Sep 2020 02:58:14 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:59

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:57:51', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '05c2e67b-e572-4a51-9200-017c9bb253fb' | System | 10 Sep 2020 02:58:14 |
| User entered 'Yes (Y)' | System | 10 Sep 2020 02:58:14 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:59

To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant was contacted to confirm new medication details. Medication was added to concomitant medication list. Thank you. | (b) (4), (b) (6) | 30 Oct 2020 13:51:18 |
| ' (Site from System). | | |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | System | 10 Sep 2020 02:58:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:58:07', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '05c2e67b-e572-4a51-9200-017c9bb253fb' | System | 10 Sep 2020 02:58:14 |
| User entered '1' | System | 10 Sep 2020 02:58:14 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:59

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant was contacted to confirm new medication details. Medication was added to concomitant medication list. Thank you. | (b) (4), (b) (6) | 30 Oct 2020 13:51:22 |
| ' (Site from System). | | |
| User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | System | 10 Sep 2020 02:58:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:58:07', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '05c2e67b-e572-4a51-9200-017c9bb253fb' | System | 10 Sep 2020 02:58:14 |
| User entered '1' | System | 10 Sep 2020 02:58:14 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:58:16', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '05c2e67b-e572-4a51-9200-017c9bb253fb' | System | 10 Sep 2020 02:58:14 |
| User entered '09 Sep 2020 21:58' | System | 10 Sep 2020 02:58:14 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '09 Sep 2020 12:00' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '10 Sep 2020 11:59' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| Data entry locked. | System | 08 Sep 2020 21:18:21 |
| User entered 'Day 3' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:45:20', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7c4c10bb-6215-4135-97f0-54639de58396' | System | 11 Sep 2020 14:45:55 |
| User entered 'Yes (Y)' | System | 11 Sep 2020 14:45:55 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:45:30', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7c4c10bb-6215-4135-97f0-54639de58396' | System | 11 Sep 2020 14:45:55 |
| User entered '97.0' | System | 11 Sep 2020 14:45:55 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:59

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:45:36', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7c4c10bb-6215-4135-97f0-54639de58396' | System | 11 Sep 2020 14:45:55 |
| User entered 'Yes (Y)' | System | 11 Sep 2020 14:45:55 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:59

To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'AS DOCUMENTED THE PATIENT TOOK TYLENOL FOR PAIN ' (Site from System). | (b) (4), (b) (6) | 31 Oct 2020 10:41:03 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | (b) (4), (b) (6) | 02 Oct 2020 16:35:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:45:45', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7c4c10bb-6215-4135-97f0-54639de58396' | System | 11 Sep 2020 14:45:55 |
| User entered '1' | System | 11 Sep 2020 14:45:55 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:59

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:45:45', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7c4c10bb-6215-4135-97f0-54639de58396' | System | 11 Sep 2020 14:45:55 |
| User entered '0' | System | 11 Sep 2020 14:45:55 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:45:54', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7c4c10bb-6215-4135-97f0-54639de58396' | System | 11 Sep 2020 14:45:55 |
| User entered '11 Sep 2020 09:45' | System | 11 Sep 2020 14:45:55 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '10 Sep 2020 12:00' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '11 Sep 2020 11:59' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| Data entry locked. | System | 08 Sep 2020 21:18:21 |
| User entered 'Day 4' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:32:38', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4b1d48a8-0bfd-4d83-95d4-56f02e646428' | System | 12 Sep 2020 15:32:52 |
| User entered 'Yes (Y)' | System | 12 Sep 2020 15:32:52 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:32:43', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4b1d48a8-0bfd-4d83-95d4-56f02e646428' | System | 12 Sep 2020 15:32:52 |
| User entered '96.1' | System | 12 Sep 2020 15:32:52 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:59

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:32:46', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4b1d48a8-0bfd-4d83-95d4-56f02e646428' | System | 12 Sep 2020 15:32:52 |
| User entered 'No (N)' | System | 12 Sep 2020 15:32:52 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:32:51', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4b1d48a8-0bfd-4d83-95d4-56f02e646428' | System | 12 Sep 2020 15:32:52 |
| User entered '12 Sep 2020 10:32' | System | 12 Sep 2020 15:32:52 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '11 Sep 2020 12:00' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '12 Sep 2020 11:59' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| Data entry locked. | System | 08 Sep 2020 21:18:21 |
| User entered 'Day 5' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:26:48', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '53461583-b8fb-472c-b315-0e330c094292' | System | 13 Sep 2020 07:27:59 |
| User entered 'Yes (Y)' | System | 13 Sep 2020 07:27:59 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:26:55', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '53461583-b8fb-472c-b315-0e330c094292' User entered '96.4' | System | 13 Sep 2020 07:27:59 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:59

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:26:59', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '53461583-b8fb-472c-b315-0e330c094292' | System | 13 Sep 2020 07:27:59 |
| User entered 'No (N)' | System | 13 Sep 2020 07:27:59 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:28:00', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '53461583-b8fb-472c-b315-0e330c094292' | System | 13 Sep 2020 07:27:59 |
| User entered '13 Sep 2020 02:28' | System | 13 Sep 2020 07:27:59 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '12 Sep 2020 12:00' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '13 Sep 2020 11:59' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| Data entry locked. | System | 08 Sep 2020 21:18:21 |
| User entered 'Day 6' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| | | |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| | | |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:59

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| | | |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:59

To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| | | |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:59

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| | | |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| | | |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '13 Sep 2020 12:00' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '14 Sep 2020 11:59' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| Data entry locked. | System | 08 Sep 2020 21:18:21 |
| User entered 'Day 7' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:59

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:55:18', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '13f92f6e-6833-4a19-90b5-bc21b7c6d8f9' | System | 15 Sep 2020 14:55:33 |
| User entered 'Yes (Y)' | System | 15 Sep 2020 14:55:33 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:59

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:55:24', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '13f92f6e-6833-4a19-90b5-bc21b7c6d8f9' | System | 15 Sep 2020 14:55:33 |
| User entered '97.0' | System | 15 Sep 2020 14:55:33 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:59

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:55:28', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '13f92f6e-6833-4a19-90b5-bc21b7c6d8f9' | System | 15 Sep 2020 14:55:33 |
| User entered 'No (N)' | System | 15 Sep 2020 14:55:33 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:55:34', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '13f92f6e-6833-4a19-90b5-bc21b7c6d8f9' | System | 15 Sep 2020 14:55:33 |
| User entered '15 Sep 2020 09:55' | System | 15 Sep 2020 14:55:33 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '14 Sep 2020 12:00' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '15 Sep 2020 11:59' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| Data entry locked. | System | 08 Sep 2020 21:18:21 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:44:59', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b21119bc-41b5-40a5-b25e-5df717a5547c' | System | 08 Sep 2020 21:45:16 |
| User entered 'None (1)' | System | 08 Sep 2020 21:45:16 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:45:03', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b21119bc-41b5-40a5-b25e-5df717a5547c' | System | 08 Sep 2020 21:45:16 |
| User entered 'No (N)' | System | 08 Sep 2020 21:45:16 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:45:06', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b21119bc-41b5-40a5-b25e-5df717a5547c' | System | 08 Sep 2020 21:45:16 |
| User entered 'No (N)' | System | 08 Sep 2020 21:45:16 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:45:12', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b21119bc-41b5-40a5-b25e-5df717a5547c' | System | 08 Sep 2020 21:45:16 |
| User entered 'None (1)' | System | 08 Sep 2020 21:45:16 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:45:16', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b21119bc-41b5-40a5-b25e-5df717a5547c' | System | 08 Sep 2020 21:45:16 |
| User entered '08 Sep 2020 16:45' | System | 08 Sep 2020 21:45:16 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '08 Sep 2020 16:29' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '08 Sep 2020 18:59' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| Data entry locked. | System | 08 Sep 2020 21:18:21 |
| User entered 'Day 1, after vaccination (at home)' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:47:15', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '6630fa1b-bc66-4ad1-96ab-924aab9fd7c0' | System | 09 Sep 2020 05:48:32 |
| User entered 'Does not interfere with activity (2)' | System | 09 Sep 2020 05:48:32 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:47:51', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '6630fa1b-bc66-4ad1-96ab-924aab9fd7c0' | System | 09 Sep 2020 05:48:32 |
| User entered 'No (N)' | System | 09 Sep 2020 05:48:32 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:47:58', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '6630fa1b-bc66-4ad1-96ab-924aab9fd7c0' | System | 09 Sep 2020 05:48:32 |
| User entered 'No (N)' | System | 09 Sep 2020 05:48:32 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:48:22', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '6630fa1b-bc66-4ad1-96ab-924aab9fd7c0' | System | 09 Sep 2020 05:48:32 |
| User entered 'None (1)' | System | 09 Sep 2020 05:48:32 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:48:30', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '6630fa1b-bc66-4ad1-96ab-924aab9fd7c0' | System | 09 Sep 2020 05:48:32 |
| User entered '09 Sep 2020 00:48' | System | 09 Sep 2020 05:48:32 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '08 Sep 2020 19:54' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '09 Sep 2020 11:59' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| Data entry locked. | System | 08 Sep 2020 21:18:21 |
| User entered 'Day 2' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:58:27', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3675b0a5-ed72-49c5-b099-9406f01a69fa' | System | 10 Sep 2020 02:59:01 |
| User entered 'Does not interfere with activity (2)' | System | 10 Sep 2020 02:59:01 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:59

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:58:29', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3675b0a5-ed72-49c5-b099-9406f01a69fa' | System | 10 Sep 2020 02:59:01 |
| User entered 'No (N)' | System | 10 Sep 2020 02:59:01 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:58:36', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3675b0a5-ed72-49c5-b099-9406f01a69fa' | System | 10 Sep 2020 02:59:01 |
| User entered 'No (N)' | System | 10 Sep 2020 02:59:01 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:58:52', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3675b0a5-ed72-49c5-b099-9406f01a69fa' | System | 10 Sep 2020 02:59:01 |
| User entered 'None (1)' | System | 10 Sep 2020 02:59:01 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:58:59', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3675b0a5-ed72-49c5-b099-9406f01a69fa' | System | 10 Sep 2020 02:59:01 |
| User entered '09 Sep 2020 21:58' | System | 10 Sep 2020 02:59:01 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '09 Sep 2020 12:00' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '10 Sep 2020 11:59' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| Data entry locked. | System | 08 Sep 2020 21:18:21 |
| User entered 'Day 3' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:46:07', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'fd036c1b-f8d5-4e5c-a6c0-a215f6f6e87d' | System | 11 Sep 2020 14:46:25 |
| User entered 'Does not interfere with activity (2)' | System | 11 Sep 2020 14:46:25 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:59

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:46:10', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'fd036c1b-f8d5-4e5c-a6c0-a215f6f6e87d' | System | 11 Sep 2020 14:46:25 |
| User entered 'No (N)' | System | 11 Sep 2020 14:46:25 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:46:13', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'fd036c1b-f8d5-4e5c-a6c0-a215f6f6e87d' | System | 11 Sep 2020 14:46:25 |
| User entered 'No (N)' | System | 11 Sep 2020 14:46:25 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:46:17', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'fd036c1b-f8d5-4e5c-a6c0-a215f6f6e87d' | System | 11 Sep 2020 14:46:25 |
| User entered 'None (1)' | System | 11 Sep 2020 14:46:25 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:46:24', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'fd036c1b-f8d5-4e5c-a6c0-a215f6f6e87d' | System | 11 Sep 2020 14:46:25 |
| User entered '11 Sep 2020 09:46' | System | 11 Sep 2020 14:46:25 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '10 Sep 2020 12:00' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '11 Sep 2020 11:59' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| Data entry locked. | System | 08 Sep 2020 21:18:21 |
| User entered 'Day 4' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:33:28', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '725e4274-6f0b-45fe-8756-8b9d8f277437' | System | 12 Sep 2020 15:33:49 |
| User entered 'Does not interfere with activity (2)' | System | 12 Sep 2020 15:33:49 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:59

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:33:32', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '725e4274-6f0b-45fe-8756-8b9d8f277437' | System | 12 Sep 2020 15:33:49 |
| User entered 'No (N)' | System | 12 Sep 2020 15:33:49 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:33:34', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '725e4274-6f0b-45fe-8756-8b9d8f277437' | System | 12 Sep 2020 15:33:49 |
| User entered 'No (N)' | System | 12 Sep 2020 15:33:49 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:33:46', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '725e4274-6f0b-45fe-8756-8b9d8f277437' | System | 12 Sep 2020 15:33:49 |
| User entered 'None (1)' | System | 12 Sep 2020 15:33:49 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:33:48', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '725e4274-6f0b-45fe-8756-8b9d8f277437' | System | 12 Sep 2020 15:33:49 |
| User entered '12 Sep 2020 10:33' | System | 12 Sep 2020 15:33:49 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '11 Sep 2020 12:00' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '12 Sep 2020 11:59' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| Data entry locked. | System | 08 Sep 2020 21:18:21 |
| User entered 'Day 5' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:28:12', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '599ed83f-43af-445a-92a1-afc1915bd337' | System | 13 Sep 2020 07:28:36 |
| User entered 'None (1)' | System | 13 Sep 2020 07:28:36 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:59

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:28:15', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '599ed83f-43af-445a-92a1-afc1915bd337' | System | 13 Sep 2020 07:28:36 |
| User entered 'No (N)' | System | 13 Sep 2020 07:28:36 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:28:18', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '599ed83f-43af-445a-92a1-afc1915bd337' | System | 13 Sep 2020 07:28:36 |
| User entered 'No (N)' | System | 13 Sep 2020 07:28:36 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:28:27', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '599ed83f-43af-445a-92a1-afc1915bd337' | System | 13 Sep 2020 07:28:36 |
| User entered 'None (1)' | System | 13 Sep 2020 07:28:36 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:28:35', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '599ed83f-43af-445a-92a1-afc1915bd337' | System | 13 Sep 2020 07:28:36 |
| User entered '13 Sep 2020 02:28' | System | 13 Sep 2020 07:28:36 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '12 Sep 2020 12:00' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '13 Sep 2020 11:59' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| Data entry locked. | System | 08 Sep 2020 21:18:21 |
| User entered 'Day 6' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| | | |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:59

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| | | |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:59

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| | | |

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Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| | | |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:59

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| | | |

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Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| | | |

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Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| | | |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '13 Sep 2020 12:00' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '14 Sep 2020 11:59' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| Data entry locked. | System | 08 Sep 2020 21:18:21 |
| User entered 'Day 7' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:55:39', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '801c192a-73ee-45d4-bc81-35686782ab54' | System | 15 Sep 2020 14:55:59 |
| User entered 'None (1)' | System | 15 Sep 2020 14:55:59 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:59

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:55:42', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '801c192a-73ee-45d4-bc81-35686782ab54' | System | 15 Sep 2020 14:55:59 |
| User entered 'No (N)' | System | 15 Sep 2020 14:55:59 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:55:47', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '801c192a-73ee-45d4-bc81-35686782ab54' | System | 15 Sep 2020 14:55:59 |
| User entered 'No (N)' | System | 15 Sep 2020 14:55:59 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:55:53', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '801c192a-73ee-45d4-bc81-35686782ab54' | System | 15 Sep 2020 14:55:59 |
| User entered 'None (1)' | System | 15 Sep 2020 14:55:59 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:59

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:56:02', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '801c192a-73ee-45d4-bc81-35686782ab54' | System | 15 Sep 2020 14:55:59 |
| User entered '15 Sep 2020 09:56' | System | 15 Sep 2020 14:55:59 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '14 Sep 2020 12:00' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '15 Sep 2020 11:59' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| Data entry locked. | System | 08 Sep 2020 21:18:21 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:45:21', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b6b437ee-9ddb-4d5f-bf0f-0c8e58b7a308' | System | 08 Sep 2020 21:45:51 |
| User entered 'None (0)' | System | 08 Sep 2020 21:45:51 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:45:25', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b6b437ee-9ddb-4d5f-bf0f-0c8e58b7a308' | System | 08 Sep 2020 21:45:51 |
| User entered 'None (0)' | System | 08 Sep 2020 21:45:51 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:45:30', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b6b437ee-9ddb-4d5f-bf0f-0c8e58b7a308' | System | 08 Sep 2020 21:45:51 |
| User entered 'None (0)' | System | 08 Sep 2020 21:45:51 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:45:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b6b437ee-9ddb-4d5f-bf0f-0c8e58b7a308' | System | 08 Sep 2020 21:45:51 |
| User entered 'None (0)' | System | 08 Sep 2020 21:45:51 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:45:36', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b6b437ee-9ddb-4d5f-bf0f-0c8e58b7a308' | System | 08 Sep 2020 21:45:51 |
| User entered 'None (0)' | System | 08 Sep 2020 21:45:51 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:45:38', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b6b437ee-9ddb-4d5f-bf0f-0c8e58b7a308' | System | 08 Sep 2020 21:45:51 |
| User entered 'None (0)' | System | 08 Sep 2020 21:45:51 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:45:44', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b6b437ee-9ddb-4d5f-bf0f-0c8e58b7a308' | System | 08 Sep 2020 21:45:51 |
| User entered 'No (N)' | System | 08 Sep 2020 21:45:51 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:45:49', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b6b437ee-9ddb-4d5f-bf0f-0c8e58b7a308' | System | 08 Sep 2020 21:45:51 |
| User entered '08 Sep 2020 16:45' | System | 08 Sep 2020 21:45:51 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '08 Sep 2020 16:29' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '08 Sep 2020 18:59' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| Data entry locked. | System | 08 Sep 2020 21:18:21 |
| User entered 'Day 1, after vaccination (at home)' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:48:35', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'bce0c0a7-6b54-4ff8-8865-67f1b9ef66bc' | System | 09 Sep 2020 05:49:06 |
| User entered 'None (0)' | System | 09 Sep 2020 05:49:06 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:48:40', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'bce0c0a7-6b54-4ff8-8865-67f1b9ef66bc' | System | 09 Sep 2020 05:49:06 |
| User entered 'None (0)' | System | 09 Sep 2020 05:49:06 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:48:45', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'bce0c0a7-6b54-4ff8-8865-67f1b9ef66bc' | System | 09 Sep 2020 05:49:06 |
| User entered 'None (0)' | System | 09 Sep 2020 05:49:06 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:48:49', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'bce0c0a7-6b54-4ff8-8865-67f1b9ef66bc' | System | 09 Sep 2020 05:49:06 |
| User entered 'None (0)' | System | 09 Sep 2020 05:49:06 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:48:52', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'bce0c0a7-6b54-4ff8-8865-67f1b9ef66bc' | System | 09 Sep 2020 05:49:06 |
| User entered 'None (0)' | System | 09 Sep 2020 05:49:06 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:48:55', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'bce0c0a7-6b54-4ff8-8865-67f1b9ef66bc' | System | 09 Sep 2020 05:49:06 |
| User entered 'None (0)' | System | 09 Sep 2020 05:49:06 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:49:02', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'bce0c0a7-6b54-4ff8-8865-67f1b9ef66bc' | System | 09 Sep 2020 05:49:06 |
| User entered 'No (N)' | System | 09 Sep 2020 05:49:06 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:49:06', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'bce0c0a7-6b54-4ff8-8865-67f1b9ef66bc' | System | 09 Sep 2020 05:49:06 |
| User entered '09 Sep 2020 00:49' | System | 09 Sep 2020 05:49:06 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '08 Sep 2020 19:54' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '09 Sep 2020 11:59' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| Data entry locked. | System | 08 Sep 2020 21:18:21 |
| User entered 'Day 2' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:59:05', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '192844a8-81a2-427d-882c-92877bf6be4a' | System | 10 Sep 2020 03:00:05 |
| User entered 'None (0)' | System | 10 Sep 2020 03:00:05 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:59:21', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '192844a8-81a2-427d-882c-92877bf6be4a' | System | 10 Sep 2020 03:00:05 |
| User entered 'None (0)' | System | 10 Sep 2020 03:00:05 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:59:28', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '192844a8-81a2-427d-882c-92877bf6be4a' | System | 10 Sep 2020 03:00:05 |
| User entered 'None (0)' | System | 10 Sep 2020 03:00:05 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:59:31', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '192844a8-81a2-427d-882c-92877bf6be4a' | System | 10 Sep 2020 03:00:05 |
| User entered 'None (0)' | System | 10 Sep 2020 03:00:05 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:59:34', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '192844a8-81a2-427d-882c-92877bf6be4a' | System | 10 Sep 2020 03:00:05 |
| User entered 'None (0)' | System | 10 Sep 2020 03:00:05 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:59:46', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '192844a8-81a2-427d-882c-92877bf6be4a' | System | 10 Sep 2020 03:00:05 |
| User entered 'No interference with activity (1)' | System | 10 Sep 2020 03:00:05 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:59:53', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '192844a8-81a2-427d-882c-92877bf6be4a' | System | 10 Sep 2020 03:00:05 |
| User entered 'No (N)' | System | 10 Sep 2020 03:00:05 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T22:00:02', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '192844a8-81a2-427d-882c-92877bf6be4a' | System | 10 Sep 2020 03:00:05 |
| User entered '09 Sep 2020 22:00' | System | 10 Sep 2020 03:00:05 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '09 Sep 2020 12:00' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '10 Sep 2020 11:59' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| Data entry locked. | System | 08 Sep 2020 21:18:21 |
| User entered 'Day 3' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:46:29', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '76f2b6f3-facf-4e6d-ba3f-763cb7bb3022' | System | 11 Sep 2020 14:47:24 |
| User entered 'None (0)' | System | 11 Sep 2020 14:47:24 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:46:36', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '76f2b6f3-facf-4e6d-ba3f-763cb7bb3022' | System | 11 Sep 2020 14:47:24 |
| User entered 'No interference with activity (1)' | System | 11 Sep 2020 14:47:24 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:46:47', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '76f2b6f3-facf-4e6d-ba3f-763cb7bb3022' | System | 11 Sep 2020 14:47:24 |
| User entered 'None (0)' | System | 11 Sep 2020 14:47:24 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:46:51', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '76f2b6f3-facf-4e6d-ba3f-763cb7bb3022' | System | 11 Sep 2020 14:47:24 |
| User entered 'None (0)' | System | 11 Sep 2020 14:47:24 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:46:53', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '76f2b6f3-facf-4e6d-ba3f-763cb7bb3022' | System | 11 Sep 2020 14:47:24 |
| User entered 'None (0)' | System | 11 Sep 2020 14:47:24 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:47:12', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '76f2b6f3-facf-4e6d-ba3f-763cb7bb3022' | System | 11 Sep 2020 14:47:24 |
| User entered 'None (0)' | System | 11 Sep 2020 14:47:24 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:47:15', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '76f2b6f3-facf-4e6d-ba3f-763cb7bb3022' | System | 11 Sep 2020 14:47:24 |
| User entered 'No (N)' | System | 11 Sep 2020 14:47:24 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:47:22', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '76f2b6f3-facf-4e6d-ba3f-763cb7bb3022' | System | 11 Sep 2020 14:47:24 |
| User entered '11 Sep 2020 09:47' | System | 11 Sep 2020 14:47:24 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '10 Sep 2020 12:00' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '11 Sep 2020 11:59' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| Data entry locked. | System | 08 Sep 2020 21:18:21 |
| User entered 'Day 4' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:32:56', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b5dc5c15-0205-4db4-8b4c-bcb30d8ba424' | System | 12 Sep 2020 15:33:18 |
| User entered 'None (0)' | System | 12 Sep 2020 15:33:18 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:32:59', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b5dc5c15-0205-4db4-8b4c-bcb30d8ba424' | System | 12 Sep 2020 15:33:18 |
| User entered 'None (0)' | System | 12 Sep 2020 15:33:18 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:33:01', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b5dc5c15-0205-4db4-8b4c-bcb30d8ba424' | System | 12 Sep 2020 15:33:18 |
| User entered 'None (0)' | System | 12 Sep 2020 15:33:18 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:33:03', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b5dc5c15-0205-4db4-8b4c-bcb30d8ba424' | System | 12 Sep 2020 15:33:18 |
| User entered 'None (0)' | System | 12 Sep 2020 15:33:18 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:33:06', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b5dc5c15-0205-4db4-8b4c-bcb30d8ba424' | System | 12 Sep 2020 15:33:18 |
| User entered 'None (0)' | System | 12 Sep 2020 15:33:18 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:33:07', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b5dc5c15-0205-4db4-8b4c-bcb30d8ba424' | System | 12 Sep 2020 15:33:18 |
| User entered 'None (0)' | System | 12 Sep 2020 15:33:18 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:33:11', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b5dc5c15-0205-4db4-8b4c-bcb30d8ba424' | System | 12 Sep 2020 15:33:18 |
| User entered 'No (N)' | System | 12 Sep 2020 15:33:18 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:33:17', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b5dc5c15-0205-4db4-8b4c-bcb30d8ba424' | System | 12 Sep 2020 15:33:18 |
| User entered '12 Sep 2020 10:33' | System | 12 Sep 2020 15:33:18 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '11 Sep 2020 12:00' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '12 Sep 2020 11:59' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| Data entry locked. | System | 08 Sep 2020 21:18:21 |
| User entered 'Day 5' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:28:42', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e58cd410-ca35-4434-9388-8c8d49f45aa1' | System | 13 Sep 2020 07:29:09 |
| User entered 'None (0)' | System | 13 Sep 2020 07:29:09 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:28:44', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e58cd410-ca35-4434-9388-8c8d49f45aa1' | System | 13 Sep 2020 07:29:09 |
| User entered 'None (0)' | System | 13 Sep 2020 07:29:09 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:28:47', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e58cd410-ca35-4434-9388-8c8d49f45aa1' | System | 13 Sep 2020 07:29:09 |
| User entered 'None (0)' | System | 13 Sep 2020 07:29:09 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:28:49', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e58cd410-ca35-4434-9388-8c8d49f45aa1' | System | 13 Sep 2020 07:29:09 |
| User entered 'None (0)' | System | 13 Sep 2020 07:29:09 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:28:51', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e58cd410-ca35-4434-9388-8c8d49f45aa1' | System | 13 Sep 2020 07:29:09 |
| User entered 'None (0)' | System | 13 Sep 2020 07:29:09 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:28:54', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e58cd410-ca35-4434-9388-8c8d49f45aa1' | System | 13 Sep 2020 07:29:09 |
| User entered 'None (0)' | System | 13 Sep 2020 07:29:09 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:29:02', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e58cd410-ca35-4434-9388-8c8d49f45aa1' | System | 13 Sep 2020 07:29:09 |
| User entered 'No (N)' | System | 13 Sep 2020 07:29:09 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:29:10', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e58cd410-ca35-4434-9388-8c8d49f45aa1' | System | 13 Sep 2020 07:29:09 |
| User entered '13 Sep 2020 02:29' | System | 13 Sep 2020 07:29:09 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '12 Sep 2020 12:00' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '13 Sep 2020 11:59' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| Data entry locked. | System | 08 Sep 2020 21:18:21 |
| User entered 'Day 6' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| | | |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| | | |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| | | |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| | | |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| | | |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| | | |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| | | |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| | | |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '13 Sep 2020 12:00' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '14 Sep 2020 11:59' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| Data entry locked. | System | 08 Sep 2020 21:18:21 |
| User entered 'Day 7' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:56:07', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '50df84d8-8a51-4063-8dd8-7d3fb24beb36' | System | 15 Sep 2020 14:56:42 |
| User entered 'None (0)' | System | 15 Sep 2020 14:56:42 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:56:15', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '50df84d8-8a51-4063-8dd8-7d3fb24beb36' | System | 15 Sep 2020 14:56:42 |
| User entered 'None (0)' | System | 15 Sep 2020 14:56:42 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:56:17', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '50df84d8-8a51-4063-8dd8-7d3fb24beb36' | System | 15 Sep 2020 14:56:42 |
| User entered 'None (0)' | System | 15 Sep 2020 14:56:42 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:56:20', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '50df84d8-8a51-4063-8dd8-7d3fb24beb36' | System | 15 Sep 2020 14:56:42 |
| User entered 'None (0)' | System | 15 Sep 2020 14:56:42 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:56:22', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '50df84d8-8a51-4063-8dd8-7d3fb24beb36' | System | 15 Sep 2020 14:56:42 |
| User entered 'None (0)' | System | 15 Sep 2020 14:56:42 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:56:25', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '50df84d8-8a51-4063-8dd8-7d3fb24beb36' | System | 15 Sep 2020 14:56:42 |
| User entered 'None (0)' | System | 15 Sep 2020 14:56:42 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:56:29', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '50df84d8-8a51-4063-8dd8-7d3fb24beb36' | System | 15 Sep 2020 14:56:42 |
| User entered 'No (N)' | System | 15 Sep 2020 14:56:42 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:56:43', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '50df84d8-8a51-4063-8dd8-7d3fb24beb36' | System | 15 Sep 2020 14:56:42 |
| User entered '15 Sep 2020 09:56' | System | 15 Sep 2020 14:56:42 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '14 Sep 2020 12:00' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:59

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:16:40 |
| User entered '15 Sep 2020 11:59' | System | 08 Sep 2020 21:18:21 |

US3252127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Nancy Torrence (b) (4) | 16 Sep 2020 04:19:52 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '15 Sep 2020' | Nancy Torrence (b) (4) | 16 Sep 2020 04:19:52 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Contact Made (CONTACT MADE)' | Nancy Torrence (b) (4) | 16 Sep 2020 04:19:52 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Nancy Torrence (b) (4) | 16 Sep 2020 04:19:52 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Nancy Torrence (b) (4) | 16 Sep 2020 04:19:59 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User entered 'I' | System | 16 Sep 2020 04:19:59 |

US3252127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Nancy Torrence (b) (4) | 23 Sep 2020 03:15:29 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '22 Sep 2020' | Nancy Torrence (b) (4) | 23 Sep 2020 03:15:29 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Contact Made (CONTACT MADE)' | Nancy Torrence (b) (4) | 23 Sep 2020 03:15:29 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Nancy Torrence (b) (4) | 23 Sep 2020 03:15:29 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Nancy Torrence (b) (4) | 23 Sep 2020 03:15:34 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User entered 'I' | System | 23 Sep 2020 03:15:34 |

US3252127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Nancy Torrence (b) (4) | 30 Sep 2020 05:05:35 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '29 Sep 2020' | Nancy Torrence (b) (4) | 30 Sep 2020 05:05:35 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Contact Made (CONTACT MADE)' | Nancy Torrence (b) (4) | 30 Sep 2020 05:05:35 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Nancy Torrence (b) (4) | 30 Sep 2020 05:05:35 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Nancy Torrence (b) (4) | 30 Sep 2020 05:05:41 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User entered 'I' | System | 30 Sep 2020 05:05:41 |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Nancy Torrence (b) (4) | 08 Oct 2020 06:20:37 |
| | (b) (4) | |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '7 Oct 2020' | Nancy Torrence (b) (4) | 08 Oct 2020 06:20:37 |
| | (b) (4) | |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Clinic (Clinic)' | Nancy Torrence (b) (4) | 08 Oct 2020 06:20:37 |
| | (b) (4) | |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'VISIT3' | System | 08 Oct 2020 06:20:37 |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Nancy Torrence (b) (4) | 08 Oct 2020 06:21:16 |
| | (b) (4) | |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '7 Oct 2020' | Nancy Torrence (b) (4) | 08 Oct 2020 06:21:16 |
| | (b) (4) | |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '15:29' | Nancy Torrence (b) (4) | 08 Oct 2020 06:21:16 |
| | (b) (4) | |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered '7 Oct 2020 15:29' | System | 08 Oct 2020 06:21:16 |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '97.6' F | Nancy Torrence (b) (4) | 08 Oct 2020 06:21:16 |
| | (b) (4) | |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Oral (Oral)' | Nancy Torrence (b) (4) | 08 Oct 2020 06:21:16 |
| | (b) (4) | |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered empty. | Nancy Torrence (b) (4) | 08 Oct 2020 06:21:16 |
| | (b) (4) | |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '68' | Nancy Torrence (b) (4) | 08 Oct 2020 06:21:16 |
| | (b) (4) | |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'bpm' | System | 08 Oct 2020 06:21:16 |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '16' | Nancy Torrence (b) (4) | 08 Oct 2020 06:21:16 |
| | (b) (4) | |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'breaths/min' | System | 08 Oct 2020 06:21:16 |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '124' | Nancy Torrence (b) (4) | 08 Oct 2020 06:21:16 |
| | (b) (4) | |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'mmHg' | System | 08 Oct 2020 06:21:16 |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '68' | Nancy Torrence (b) (4) | 08 Oct 2020 06:21:16 |
| | (b) (4) | |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'mmHg' | System | 08 Oct 2020 06:21:16 |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| | | |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| | | |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:59

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Nancy Torrence (b) (4) | 08 Oct 2020 06:21:36 |
| | (b) (4) | |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:59

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '7 Oct 2020' | Nancy Torrence (b) (4) | 08 Oct 2020 06:21:36 |
| | (b) (4) | |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:59

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Nancy Torrence (b) (4) | 08 Oct 2020 06:21:55 |
| | (b) (4) | |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:59

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 07OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM). | (b) (4), (b) (6) | 03 Nov 2020 05:39:18 |
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 07OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'It is under unscheduled visit due to 0 quantity of kit type A. As per PPD GSS, we can use kit type UV for backup. US3252127 visit is recorded correctly in EDC.' (Site from DM). | (b) (4), (b) (6) | 23 Oct 2020 17:42:46 |
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 07OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM). | (b) (4), (b) (6) | 23 Oct 2020 10:26:55 |
| User entered '7 Oct 2020' | Nancy Torrence (b) (4) (b) (4) | 08 Oct 2020 06:21:55 |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:59

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered '15:56' | Nancy Torrence (b) (4) | 08 Oct 2020 06:21:55 |
| | (b) (4) | |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:59

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered '7 Oct 2020 15:56' | System | 08 Oct 2020 06:21:55 |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User signature succeeded. | Joel Solis (b) (4) | 04 Mar 2021 23:57:56 |
| User entered 'Yes (Y)' | Nancy Torrence (b) (4) | 08 Oct 2020 06:22:00 |
| | (b) (4) | |

US3252127

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:26 |
| User entered 'I' | System | 08 Oct 2020 06:22:00 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 64' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-10-14T18:56:32', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '6863ad14-54a9-41b8-b905-469f8fbcfb72' | System | 14 Oct 2020 23:57:13 |
| User entered 'No (N)' | System | 14 Oct 2020 23:57:13 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-10-14T18:56:41', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '6863ad14-54a9-41b8-b905-469f8fbcfb72' | System | 14 Oct 2020 23:57:13 |
| User entered 'No (N)' | System | 14 Oct 2020 23:57:13 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-10-14T18:57:12', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '6863ad14-54a9-41b8-b905-469f8fbcb72' | System | 14 Oct 2020 23:57:13 |
| User entered '14 Oct 2020 18:57:12' | System | 14 Oct 2020 23:57:13 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered '11 Oct 2020 00:01' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered '15 Oct 2020 23:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 71' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-10-20T12:17:48', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '97b1fc2e-4f95-44f2-b326-4464f6ece751' | System | 20 Oct 2020 17:18:04 |
| User entered 'No (N)' | System | 20 Oct 2020 17:18:04 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-10-20T12:17:54', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '97b1fc2e-4f95-44f2-b326-4464f6ece751' | System | 20 Oct 2020 17:18:04 |
| User entered 'No (N)' | System | 20 Oct 2020 17:18:04 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-10-20T12:18:01', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '97b1fc2e-4f95-44f2-b326-4464f6ece751' | System | 20 Oct 2020 17:18:04 |
| User entered '20 Oct 2020 12:18:01' | System | 20 Oct 2020 17:18:04 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered '18 Oct 2020 00:01' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered '22 Oct 2020 23:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 78' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-10-26T11:38:22', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '8d4187fe-12fc-4088-9a83-a73beda94d1e' | System | 26 Oct 2020 16:38:38 |
| User entered 'No (N)' | System | 26 Oct 2020 16:38:38 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-10-26T11:38:27', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '8d4187fe-12fc-4088-9a83-a73beda94d1e' | System | 26 Oct 2020 16:38:38 |
| User entered 'No (N)' | System | 26 Oct 2020 16:38:38 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-10-26T11:38:35', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '8d4187fe-12fc-4088-9a83-a73beda94d1e' | System | 26 Oct 2020 16:38:38 |
| User entered '26 Oct 2020 11:38:35' | System | 26 Oct 2020 16:38:38 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered '25 Oct 2020 00:01' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered '29 Oct 2020 23:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 92' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Chills](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Cough](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Fatigue](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Muscle aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Body aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Headache](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[New loss of taste](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[New loss of smell](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Sore throat](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Congestion](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Runny nose](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Nausea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Vomiting](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered '08 Nov 2020 00:01' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 04:23:06 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered '12 Nov 2020 23:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered 'Day 99' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:49:12', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976' | System | 15 Nov 2020 21:52:37 |
| User entered 'Yes (Y)' | System | 15 Nov 2020 21:52:37 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:49:22', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976' | System | 15 Nov 2020 21:52:37 |
| User entered 'No (N)' | System | 15 Nov 2020 21:52:37 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| User closed query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). Query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'Reports symptoms of fatigue and SOB, however, patient has a history of asthma and states symptoms are no different from baseline. Patient states he has not been exposed to anyone with COVID-19. Patient will be brought into clinic later today for a rapid COVID-19 test just to rule out COVID-19.' (Site from DM). | (b) (4), (b) (6) | 30 Mar 2021 11:43:39 |
| Query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'Reports symptoms of fatigue and SOB, however, patient has a history of asthma and states symptoms are no different from baseline. Patient states he has not been exposed to anyone with COVID-19. Patient will be brought into clinic later today for a rapid COVID-19 test just to rule out COVID-19.' (Site from DM). | (b) (4), (b) (6) | 25 Mar 2021 03:26:20 |
| User opened query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 18 Dec 2020 11:36:42 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:49:35', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976' | System | 15 Nov 2020 21:52:37 |
| User entered 'Yes (Y)' | System | 15 Nov 2020 21:52:37 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976' | System | 15 Nov 2020 21:52:37 |
| User entered '0' | System | 15 Nov 2020 21:52:37 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Chills](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976' | System | 15 Nov 2020 21:52:37 |
| User entered '1' | System | 15 Nov 2020 21:52:37 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Cough](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976' | System | 15 Nov 2020 21:52:37 |
| User entered '0' | System | 15 Nov 2020 21:52:37 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976' | System | 15 Nov 2020 21:52:37 |
| User entered '1' | System | 15 Nov 2020 21:52:37 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976' | System | 15 Nov 2020 21:52:37 |
| User entered '0' | System | 15 Nov 2020 21:52:37 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Fatigue](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976' | System | 15 Nov 2020 21:52:37 |
| User entered '1' | System | 15 Nov 2020 21:52:37 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Muscle aches](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976' | System | 15 Nov 2020 21:52:37 |
| User entered '0' | System | 15 Nov 2020 21:52:37 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Body aches](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976' | System | 15 Nov 2020 21:52:37 |
| User entered '0' | System | 15 Nov 2020 21:52:37 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Headache](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976' | System | 15 Nov 2020 21:52:37 |
| User entered '0' | System | 15 Nov 2020 21:52:37 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[New loss of taste](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976' | System | 15 Nov 2020 21:52:37 |
| User entered '0' | System | 15 Nov 2020 21:52:37 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[New loss of smell](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976' | System | 15 Nov 2020 21:52:37 |
| User entered '0' | System | 15 Nov 2020 21:52:37 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Sore throat](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976' | System | 15 Nov 2020 21:52:37 |
| User entered '0' | System | 15 Nov 2020 21:52:37 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Congestion](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976' | System | 15 Nov 2020 21:52:37 |
| User entered '0' | System | 15 Nov 2020 21:52:37 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Runny nose](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976' | System | 15 Nov 2020 21:52:37 |
| User entered '0' | System | 15 Nov 2020 21:52:37 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Nausea](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976' | System | 15 Nov 2020 21:52:37 |
| User entered '0' | System | 15 Nov 2020 21:52:37 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Vomiting](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976' | System | 15 Nov 2020 21:52:37 |
| User entered '0' | System | 15 Nov 2020 21:52:37 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Diarrhea](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976' | System | 15 Nov 2020 21:52:37 |
| User entered '0' | System | 15 Nov 2020 21:52:37 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:37', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976' | System | 15 Nov 2020 21:52:37 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 15 Nov 2020 21:52:37 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:52:06', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976' | System | 15 Nov 2020 21:52:37 |
| User entered 'Yes (Y)' | System | 15 Nov 2020 21:52:37 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:56', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976' | System | 15 Nov 2020 21:52:37 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 15 Nov 2020 21:52:37 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:52:24', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976' | System | 15 Nov 2020 21:52:37 |
| User entered '15 Nov 2020 15:52:24' | System | 15 Nov 2020 21:52:37 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered '15 Nov 2020 00:01' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:03:07 |
| Data entry locked. | System | 11 Aug 2020 23:07:38 |
| User entered '19 Nov 2020 23:59' | System | 11 Aug 2020 23:07:38 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-23T14:29:13', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7c217d5c-aa23-47aa-9ad7-ec1385f77a82' | System | 23 Nov 2020 20:29:23 |
| User entered 'No (N)' | System | 23 Nov 2020 20:29:23 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-23T14:29:17', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7c217d5c-aa23-47aa-9ad7-ec1385f77a82' | System | 23 Nov 2020 20:29:23 |
| User entered 'No (N)' | System | 23 Nov 2020 20:29:23 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-23T14:29:22', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7c217d5c-aa23-47aa-9ad7-ec1385f77a82' | System | 23 Nov 2020 20:29:23 |
| User entered '23 Nov 2020 14:29:22' | System | 23 Nov 2020 20:29:23 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '19 Nov 2020 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '23 Nov 2020 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-29T17:55:32', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b7be3300-9e8e-4ba2-9f6a-e6b37809d7ec' | System | 29 Nov 2020 23:55:42 |
| User entered 'No (N)' | System | 29 Nov 2020 23:55:42 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-29T17:55:36', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b7be3300-9e8e-4ba2-9f6a-e6b37809d7ec' | System | 29 Nov 2020 23:55:42 |
| User entered 'No (N)' | System | 29 Nov 2020 23:55:42 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-29T17:55:41', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b7be3300-9e8e-4ba2-9f6a-e6b37809d7ec' | System | 29 Nov 2020 23:55:42 |
| User entered '29 Nov 2020 17:55:41' | System | 29 Nov 2020 23:55:42 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '26 Nov 2020 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '30 Nov 2020 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-12-04T18:42:05', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '10186fc4-002b-48d2-8b17-c1a01bb6372b' | System | 05 Dec 2020 00:42:15 |
| User entered 'No (N)' | System | 05 Dec 2020 00:42:15 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-12-04T18:42:08', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '10186fc4-002b-48d2-8b17-c1a01bb6372b' | System | 05 Dec 2020 00:42:15 |
| User entered 'No (N)' | System | 05 Dec 2020 00:42:15 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-12-04T18:42:13', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '10186fc4-002b-48d2-8b17-c1a01bb6372b' | System | 05 Dec 2020 00:42:15 |
| User entered '04 Dec 2020 18:42:13' | System | 05 Dec 2020 00:42:15 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '03 Dec 2020 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '07 Dec 2020 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-12-13T10:49:37', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd944a43d-19e9-4b40-a9a4-8fe602be748d' | System | 13 Dec 2020 16:49:45 |
| User entered 'No (N)' | System | 13 Dec 2020 16:49:45 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-12-13T10:49:41', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd944a43d-19e9-4b40-a9a4-8fe602be748d' | System | 13 Dec 2020 16:49:45 |
| User entered 'No (N)' | System | 13 Dec 2020 16:49:45 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-12-13T10:49:44', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd944a43d-19e9-4b40-a9a4-8fe602be748d' User entered '13 Dec 2020 10:49:44' | System | 13 Dec 2020 16:49:45 |
| | System | 13 Dec 2020 16:49:45 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '10 Dec 2020 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '14 Dec 2020 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-12-21T14:02:21', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b83e7022-8866-4004-a75f-d5890db8d615' | System | 21 Dec 2020 20:02:35 |
| User entered 'No (N)' | System | 21 Dec 2020 20:02:35 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-12-21T14:02:30', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b83e7022-8866-4004-a75f-d5890db8d615' | System | 21 Dec 2020 20:02:35 |
| User entered 'No (N)' | System | 21 Dec 2020 20:02:35 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-12-21T14:02:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b83e7022-8866-4004-a75f-d5890db8d615' User entered '21 Dec 2020 14:02:33' | System | 21 Dec 2020 20:02:35 |
| | System | 21 Dec 2020 20:02:35 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '17 Dec 2020 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '21 Dec 2020 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-12-27T20:37:18', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7119a532-ae3e-466a-9b55-e3718e950204' | System | 28 Dec 2020 02:37:30 |
| User entered 'No (N)' | System | 28 Dec 2020 02:37:30 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-12-27T20:37:22', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7119a532-ae3e-466a-9b55-e3718e950204' | System | 28 Dec 2020 02:37:30 |
| User entered 'No (N)' | System | 28 Dec 2020 02:37:30 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-12-27T20:37:28', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7119a532-ae3e-466a-9b55-e3718e950204' | System | 28 Dec 2020 02:37:30 |
| User entered '27 Dec 2020 20:37:28' | System | 28 Dec 2020 02:37:30 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '24 Dec 2020 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '28 Dec 2020 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-03T13:05:11', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '322f89e1-7a02-4c7a-8851-441211561cf8' | System | 03 Jan 2021 19:06:43 |
| User entered 'Yes (Y)' | System | 03 Jan 2021 19:06:43 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-03T13:05:18', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '322f89e1-7a02-4c7a-8851-441211561cf8' | System | 03 Jan 2021 19:06:43 |
| User entered 'No (N)' | System | 03 Jan 2021 19:06:43 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-03T13:05:25', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '322f89e1-7a02-4c7a-8851-441211561cf8' | System | 03 Jan 2021 19:06:43 |
| User entered 'Yes (Y)' | System | 03 Jan 2021 19:06:43 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-03T13:05:27', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '322f89e1-7a02-4c7a-8851-441211561cf8' User entered '0' | System | 03 Jan 2021 19:06:43 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Chills](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-03T13:05:27', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '322f89e1-7a02-4c7a-8851-441211561cf8' | System | 03 Jan 2021 19:06:43 |
| User entered '1' | System | 03 Jan 2021 19:06:43 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Cough](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-03T13:05:27', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '322f89e1-7a02-4c7a-8851-441211561cf8' | System | 03 Jan 2021 19:06:43 |
| User entered '0' | System | 03 Jan 2021 19:06:43 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-03T13:05:27', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '322f89e1-7a02-4c7a-8851-441211561cf8' | System | 03 Jan 2021 19:06:43 |
| User entered '0' | System | 03 Jan 2021 19:06:43 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-03T13:05:27', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '322f89e1-7a02-4c7a-8851-441211561cf8' | System | 03 Jan 2021 19:06:43 |
| User entered '0' | System | 03 Jan 2021 19:06:43 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Fatigue](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-03T13:05:27', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '322f89e1-7a02-4c7a-8851-441211561cf8' | System | 03 Jan 2021 19:06:43 |
| User entered '0' | System | 03 Jan 2021 19:06:43 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Muscle aches](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-03T13:05:27', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '322f89e1-7a02-4c7a-8851-441211561cf8' | System | 03 Jan 2021 19:06:43 |
| User entered '0' | System | 03 Jan 2021 19:06:43 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Body aches](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-03T13:05:27', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '322f89e1-7a02-4c7a-8851-441211561cf8' | System | 03 Jan 2021 19:06:43 |
| User entered '0' | System | 03 Jan 2021 19:06:43 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Headache](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-03T13:05:27', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '322f89e1-7a02-4c7a-8851-441211561cf8' | System | 03 Jan 2021 19:06:43 |
| User entered '0' | System | 03 Jan 2021 19:06:43 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[New loss of taste](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-03T13:05:27', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '322f89e1-7a02-4c7a-8851-441211561cf8' | System | 03 Jan 2021 19:06:43 |
| User entered '0' | System | 03 Jan 2021 19:06:43 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[New loss of smell](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-03T13:05:27', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '322f89e1-7a02-4c7a-8851-441211561cf8' | System | 03 Jan 2021 19:06:43 |
| User entered '0' | System | 03 Jan 2021 19:06:43 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Sore throat](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-03T13:05:27', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '322f89e1-7a02-4c7a-8851-441211561cf8' | System | 03 Jan 2021 19:06:43 |
| User entered '0' | System | 03 Jan 2021 19:06:43 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Congestion](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-03T13:05:27', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '322f89e1-7a02-4c7a-8851-441211561cf8' | System | 03 Jan 2021 19:06:43 |
| User entered '0' | System | 03 Jan 2021 19:06:43 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Runny nose](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-03T13:05:27', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '322f89e1-7a02-4c7a-8851-441211561cf8' | System | 03 Jan 2021 19:06:43 |
| User entered '0' | System | 03 Jan 2021 19:06:43 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Nausea](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-03T13:05:27', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '322f89e1-7a02-4c7a-8851-441211561cf8' | System | 03 Jan 2021 19:06:43 |
| User entered '0' | System | 03 Jan 2021 19:06:43 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Vomiting](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-03T13:05:27', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '322f89e1-7a02-4c7a-8851-441211561cf8' | System | 03 Jan 2021 19:06:43 |
| User entered '0' | System | 03 Jan 2021 19:06:43 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Diarrhea](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-03T13:05:27', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '322f89e1-7a02-4c7a-8851-441211561cf8' | System | 03 Jan 2021 19:06:43 |
| User entered '0' | System | 03 Jan 2021 19:06:43 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-03T13:05:35', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '322f89e1-7a02-4c7a-8851-441211561cf8' | System | 03 Jan 2021 19:06:43 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 03 Jan 2021 19:06:43 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-03T13:06:12', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '322f89e1-7a02-4c7a-8851-441211561cf8' | System | 03 Jan 2021 19:06:43 |
| User entered 'No (N)' | System | 03 Jan 2021 19:06:43 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-03T13:06:34', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '322f89e1-7a02-4c7a-8851-441211561cf8' User entered '03 Jan 2021 13:06:34' | System | 03 Jan 2021 19:06:43 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '31 Dec 2020 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '04 Jan 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-11T08:59:18', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'a57a6134-f3a2-4c87-a711-27c8ed5c38e8' | System | 11 Jan 2021 14:59:30 |
| User entered 'No (N)' | System | 11 Jan 2021 14:59:30 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-11T08:59:23', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'a57a6134-f3a2-4c87-a711-27c8ed5c38e8' | System | 11 Jan 2021 14:59:30 |
| User entered 'No (N)' | System | 11 Jan 2021 14:59:30 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-11T08:59:27', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'a57a6134-f3a2-4c87-a711-27c8ed5c38e8' User entered '11 Jan 2021 08:59:27' | System | 11 Jan 2021 14:59:30 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '07 Jan 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '11 Jan 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-15T10:21:49', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2b58e37b-716f-4d25-9fd7-517b090ea3ee' | System | 15 Jan 2021 16:21:57 |
| User entered 'No (N)' | System | 15 Jan 2021 16:21:57 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-15T10:21:55', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2b58e37b-716f-4d25-9fd7-517b090ea3ee' | System | 15 Jan 2021 16:21:57 |
| User entered 'No (N)' | System | 15 Jan 2021 16:21:57 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-15T10:21:59', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2b58e37b-716f-4d25-9fd7-517b090ea3ee' | System | 15 Jan 2021 16:21:57 |
| User entered '15 Jan 2021 10:21:59' | System | 15 Jan 2021 16:21:57 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '14 Jan 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '18 Jan 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-22T15:07:09', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'ebdab671-e70e-4e09-abad-eb8a69402ce4' | System | 22 Jan 2021 21:07:19 |
| User entered 'No (N)' | System | 22 Jan 2021 21:07:19 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-22T15:07:15', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'ebdab671-e70e-4e09-abad-eb8a69402ce4' | System | 22 Jan 2021 21:07:19 |
| User entered 'No (N)' | System | 22 Jan 2021 21:07:19 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-22T15:07:20', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'ebdab671-e70e-4e09-abad-eb8a69402ce4' User entered '22 Jan 2021 15:07:20' | System | 22 Jan 2021 21:07:19 |
| | System | 22 Jan 2021 21:07:19 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '21 Jan 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '25 Jan 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-28T13:21:29', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7d1ebb2d-edc2-41c1-a4d1-0711e290fe84' | System | 28 Jan 2021 19:21:34 |
| User entered 'No (N)' | System | 28 Jan 2021 19:21:34 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-28T13:21:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7d1ebb2d-edc2-41c1-a4d1-0711e290fe84' | System | 28 Jan 2021 19:21:34 |
| User entered 'No (N)' | System | 28 Jan 2021 19:21:34 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-01-28T13:21:36', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7d1ebb2d-edc2-41c1-a4d1-0711e290fe84' | System | 28 Jan 2021 19:21:34 |
| User entered '28 Jan 2021 13:21:36' | System | 28 Jan 2021 19:21:34 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '28 Jan 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '01 Feb 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-02-07T16:02:43', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '99356bfc-590a-4d7a-92de-6bf6cf2be0f4' | System | 07 Feb 2021 22:03:02 |
| User entered 'No (N)' | System | 07 Feb 2021 22:03:02 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-02-07T16:02:53', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '99356bfc-590a-4d7a-92de-6bf6cf2be0f4' | System | 07 Feb 2021 22:03:02 |
| User entered 'No (N)' | System | 07 Feb 2021 22:03:02 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-02-07T16:02:59', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '99356bfc-590a-4d7a-92de-6bf6cf2be0f4' | System | 07 Feb 2021 22:03:02 |
| User entered '07 Feb 2021 16:02:59' | System | 07 Feb 2021 22:03:02 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '04 Feb 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '08 Feb 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-02-13T12:08:55', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3800c3cd-3200-4d0c-b210-caf85021500c' | System | 13 Feb 2021 18:11:54 |
| User entered 'No (N)' | System | 13 Feb 2021 18:11:54 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-02-13T12:09:08', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3800c3cd-3200-4d0c-b210-caf85021500c' | System | 13 Feb 2021 18:11:54 |
| User entered 'No (N)' | System | 13 Feb 2021 18:11:54 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-02-13T12:09:12', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3800c3cd-3200-4d0c-b210-caf85021500c' User entered '13 Feb 2021 12:09:12' | System | 13 Feb 2021 18:11:54 |
| | System | 13 Feb 2021 18:11:54 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '11 Feb 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '15 Feb 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-02-20T10:03:19', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'af65e835-e1f6-4193-8676-cb0c85909081' | System | 20 Feb 2021 16:03:39 |
| User entered 'No (N)' | System | 20 Feb 2021 16:03:39 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-02-20T10:03:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'af65e835-e1f6-4193-8676-cb0c85909081' | System | 20 Feb 2021 16:03:39 |
| User entered 'No (N)' | System | 20 Feb 2021 16:03:39 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-02-20T10:03:36', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'af65e835-e1f6-4193-8676-cb0c85909081' | System | 20 Feb 2021 16:03:39 |
| User entered '20 Feb 2021 10:03:36' | System | 20 Feb 2021 16:03:39 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '18 Feb 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '22 Feb 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-02-27T17:49:10', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e584dc97-00ce-47c1-bfad-37f990571571' | System | 27 Feb 2021 23:49:26 |
| User entered 'No (N)' | System | 27 Feb 2021 23:49:26 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-02-27T17:49:20', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e584dc97-00ce-47c1-bfad-37f990571571' | System | 27 Feb 2021 23:49:26 |
| User entered 'No (N)' | System | 27 Feb 2021 23:49:26 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-02-27T17:49:26', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e584dc97-00ce-47c1-bfad-37f990571571' | System | 27 Feb 2021 23:49:26 |
| User entered '27 Feb 2021 17:49:26' | System | 27 Feb 2021 23:49:26 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '25 Feb 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '01 Mar 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-03-05T14:45:47', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '97b1c4a0-bf12-49ad-b706-45078b6c0dd8' | System | 05 Mar 2021 23:15:30 |
| User entered 'No (N)' | System | 05 Mar 2021 23:15:30 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-03-05T14:45:52', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '97b1c4a0-bf12-49ad-b706-45078b6c0dd8' | System | 05 Mar 2021 23:15:30 |
| User entered 'No (N)' | System | 05 Mar 2021 23:15:30 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-03-05T14:45:56', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '97b1c4a0-bf12-49ad-b706-45078b6c0dd8' | System | 05 Mar 2021 23:15:30 |
| User entered '05 Mar 2021 14:45:56' | System | 05 Mar 2021 23:15:30 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '04 Mar 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '08 Mar 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-03-11T14:05:37', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '0239bdb3-ba93-407e-b2cc-41a59b72d3f1' | System | 11 Mar 2021 20:05:53 |
| User entered 'No (N)' | System | 11 Mar 2021 20:05:53 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-03-11T14:05:43', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '0239bdb3-ba93-407e-b2cc-41a59b72d3f1' | System | 11 Mar 2021 20:05:53 |
| User entered 'No (N)' | System | 11 Mar 2021 20:05:53 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-03-11T14:05:47', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '0239bdb3-ba93-407e-b2cc-41a59b72d3f1' | System | 11 Mar 2021 20:05:53 |
| User entered '11 Mar 2021 14:05:47' | System | 11 Mar 2021 20:05:53 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '11 Mar 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '15 Mar 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-03-20T09:21:55', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '1e447f70-2717-4990-829b-b1afa74a9119' | System | 20 Mar 2021 14:22:08 |
| User entered 'No (N)' | System | 20 Mar 2021 14:22:08 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-03-20T09:21:59', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '1e447f70-2717-4990-829b-b1afa74a9119' | System | 20 Mar 2021 14:22:08 |
| User entered 'No (N)' | System | 20 Mar 2021 14:22:08 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-03-20T09:22:03', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '1e447f70-2717-4990-829b-b1afa74a9119' | System | 20 Mar 2021 14:22:08 |
| User entered '20 Mar 2021 09:22:03' | System | 20 Mar 2021 14:22:08 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '18 Mar 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '22 Mar 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-03-29T14:54:40', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '1d897330-fe22-4906-8ece-9a4e62083e8d' | System | 29 Mar 2021 19:54:53 |
| User entered 'No (N)' | System | 29 Mar 2021 19:54:53 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-03-29T14:54:44', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '1d897330-fe22-4906-8ece-9a4e62083e8d' | System | 29 Mar 2021 19:54:53 |
| User entered 'No (N)' | System | 29 Mar 2021 19:54:53 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-03-29T14:54:47', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '1d897330-fe22-4906-8ece-9a4e62083e8d' User entered '29 Mar 2021 14:54:47' | System | 29 Mar 2021 19:54:53 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '25 Mar 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '29 Mar 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-04-05T19:18:51', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd3ca548e-b89f-478b-a2fe-48eb3384954d' | System | 06 Apr 2021 00:19:02 |
| User entered 'No (N)' | System | 06 Apr 2021 00:19:02 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-04-05T19:18:56', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd3ca548e-b89f-478b-a2fe-48eb3384954d' | System | 06 Apr 2021 00:19:02 |
| User entered 'No (N)' | System | 06 Apr 2021 00:19:02 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-04-05T19:18:59', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd3ca548e-b89f-478b-a2fe-48eb3384954d' | System | 06 Apr 2021 00:19:02 |
| User entered '05 Apr 2021 19:18:59' | System | 06 Apr 2021 00:19:02 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '01 Apr 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '05 Apr 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-04-11T22:49:56', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2bf04120-bed9-4cd5-860a-4f43678d965d' | System | 12 Apr 2021 03:50:47 |
| User entered 'No (N)' | System | 12 Apr 2021 03:50:47 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-04-11T22:50:02', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2bf04120-bed9-4cd5-860a-4f43678d965d' | System | 12 Apr 2021 03:50:47 |
| User entered 'No (N)' | System | 12 Apr 2021 03:50:47 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-04-11T22:50:05', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2bf04120-bed9-4cd5-860a-4f43678d965d' | System | 12 Apr 2021 03:50:47 |
| User entered '11 Apr 2021 22:50:05' | System | 12 Apr 2021 03:50:47 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '08 Apr 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '12 Apr 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-04-17T14:05:51', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'c373e024-b7a6-4c92-a9f0-215b9478eec2' | System | 17 Apr 2021 19:06:01 |
| User entered 'No (N)' | System | 17 Apr 2021 19:06:01 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-04-17T14:05:56', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'c373e024-b7a6-4c92-a9f0-215b9478eec2' | System | 17 Apr 2021 19:06:01 |
| User entered 'No (N)' | System | 17 Apr 2021 19:06:01 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-04-17T14:05:58', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'c373e024-b7a6-4c92-a9f0-215b9478eec2' User entered '17 Apr 2021 14:05:58' | System | 17 Apr 2021 19:06:01 |
| | System | 17 Apr 2021 19:06:01 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '15 Apr 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '19 Apr 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-04-22T21:31:47', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '8226fe25-2e6d-407c-bea6-c0bb859893cb' | System | 23 Apr 2021 02:31:58 |
| User entered 'No (N)' | System | 23 Apr 2021 02:31:58 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-04-22T21:31:52', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '8226fe25-2e6d-407c-bea6-c0bb859893cb' | System | 23 Apr 2021 02:31:58 |
| User entered 'No (N)' | System | 23 Apr 2021 02:31:58 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-04-22T21:31:56', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '8226fe25-2e6d-407c-bea6-c0bb859893cb' | System | 23 Apr 2021 02:31:58 |
| User entered '22 Apr 2021 21:31:56' | System | 23 Apr 2021 02:31:58 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '22 Apr 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '26 Apr 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-05-03T23:18:57', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'fdad6db9-5403-4569-9b0c-b54fe379670e' | System | 04 May 2021 04:19:07 |
| User entered 'No (N)' | System | 04 May 2021 04:19:07 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-05-03T23:19:00', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'fdad6db9-5403-4569-9b0c-b54fe379670e' | System | 04 May 2021 04:19:07 |
| User entered 'No (N)' | System | 04 May 2021 04:19:07 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-05-03T23:19:02', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'fdad6db9-5403-4569-9b0c-b54fe379670e' | System | 04 May 2021 04:19:07 |
| User entered '03 May 2021 23:19:02' | System | 04 May 2021 04:19:07 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '29 Apr 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '03 May 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '06 May 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '10 May 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '13 May 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '17 May 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '20 May 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '24 May 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '27 May 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '31 May 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '03 Jun 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '07 Jun 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '10 Jun 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '14 Jun 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '17 Jun 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '21 Jun 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '24 Jun 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '28 Jun 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '01 Jul 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '05 Jul 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '08 Jul 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '12 Jul 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '15 Jul 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '19 Jul 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '22 Jul 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '26 Jul 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '29 Jul 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '02 Aug 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '05 Aug 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '09 Aug 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '12 Aug 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '16 Aug 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '19 Aug 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '23 Aug 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '26 Aug 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '30 Aug 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '02 Sep 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '06 Sep 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '09 Sep 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '13 Sep 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '16 Sep 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '20 Sep 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '23 Sep 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '27 Sep 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '30 Sep 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '04 Oct 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '07 Oct 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '11 Oct 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '14 Oct 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '18 Oct 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '21 Oct 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '25 Oct 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '28 Oct 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '01 Nov 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '04 Nov 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '08 Nov 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '11 Nov 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '15 Nov 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '18 Nov 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '22 Nov 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '25 Nov 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '29 Nov 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '02 Dec 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '06 Dec 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '09 Dec 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '13 Dec 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '16 Dec 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '20 Dec 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '23 Dec 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '27 Dec 2021 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '30 Dec 2021 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '03 Jan 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '06 Jan 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '10 Jan 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '13 Jan 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '17 Jan 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '20 Jan 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '24 Jan 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '27 Jan 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '31 Jan 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '03 Feb 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '07 Feb 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '10 Feb 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '14 Feb 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '17 Feb 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '21 Feb 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '24 Feb 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '28 Feb 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '03 Mar 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '07 Mar 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '10 Mar 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '14 Mar 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '17 Mar 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '21 Mar 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '24 Mar 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '28 Mar 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '31 Mar 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '04 Apr 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '07 Apr 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '11 Apr 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '14 Apr 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '18 Apr 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '21 Apr 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '25 Apr 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '28 Apr 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '02 May 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '05 May 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '09 May 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '12 May 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '16 May 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '19 May 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '23 May 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '26 May 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '30 May 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '02 Jun 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '06 Jun 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '09 Jun 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '13 Jun 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '16 Jun 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '20 Jun 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '23 Jun 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '27 Jun 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '30 Jun 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '04 Jul 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '07 Jul 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '11 Jul 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '14 Jul 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '18 Jul 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '21 Jul 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '25 Jul 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '28 Jul 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '01 Aug 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '04 Aug 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '08 Aug 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '11 Aug 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '15 Aug 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '18 Aug 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '22 Aug 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '25 Aug 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '29 Aug 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '01 Sep 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '05 Sep 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '08 Sep 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '12 Sep 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '15 Sep 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '19 Sep 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '22 Sep 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '26 Sep 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '29 Sep 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '03 Oct 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '06 Oct 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '10 Oct 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '13 Oct 2022 00:01' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:59

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 04:23:06 |
| Amendment Manager: User entered '17 Oct 2022 23:59' | System | 19 Nov 2020 04:23:06 |

US3252127

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:09:59

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 13:54:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-02-27T17:50:12', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '28e85800-b5b0-439c-bb70-0485ed91022b' | System | 27 Feb 2021 23:50:26 |
| User entered 'No (N)' | System | 27 Feb 2021 23:50:26 |

US3252127

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:09:59

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 13:54:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2021-02-27T17:50:26', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '28e85800-b5b0-439c-bb70-0485ed91022b' | System | 27 Feb 2021 23:50:26 |
| User entered '27 Feb 2021 17:50:26' | System | 27 Feb 2021 23:50:26 |

US3252127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Nancy Torrence (b) (4) | 04 Nov 2020 02:39:00 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '3 Nov 2020' | Nancy Torrence (b) (4) | 04 Nov 2020 02:39:00 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Contact Made (CONTACT MADE)' | Nancy Torrence (b) (4) | 04 Nov 2020 02:39:00 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Nancy Torrence (b) (4) | 04 Nov 2020 02:39:00 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Nancy Torrence (b) (4) | 04 Nov 2020 02:39:04 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 01:43:01 |
| User entered 'I' | System | 04 Nov 2020 02:39:04 |

US3252127

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 08 Dec 2020 03:02:44 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '7 Dec 2020' | Shannon Moyer (b) (4) | 08 Dec 2020 03:02:44 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Contact Made (CONTACT MADE)' | Shannon Moyer (b) (4) | 08 Dec 2020 03:02:44 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 08 Dec 2020 03:02:44 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 08 Dec 2020 03:02:49 |
| | (b) (4) | |

US3252127

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User entered 'I' | System | 08 Dec 2020 03:02:49 |

US3252127

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 05 Feb 2021 03:38:32 |

US3252127

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '6 Jan 2021' | Joanna Gurrola Mahoney (b) (4) | 05 Feb 2021 03:38:32 |

US3252127

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Contact Not Made (CONTACT NOT MADE)' | Joanna Gurrola Mahoney (b) (4) | 05 Feb 2021 03:38:32 |

US3252127

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'left voice mail' | Joanna Gurrola Mahoney (b) (4) | 05 Feb 2021 03:38:32 |

US3252127

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 05 Feb 2021 03:38:36 |

US3252127

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User entered 'I' | System | 05 Feb 2021 03:38:36 |

US3252127

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 08 Feb 2021 02:37:40 |

US3252127

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '6 Feb 2021' | (b) (4), (b) (6) | 08 Feb 2021 02:37:40 |

US3252127

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 08 Feb 2021 02:37:40 |

US3252127

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | (b) (4), (b) (6) | 08 Feb 2021 02:37:40 |

US3252127

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 08 Feb 2021 02:37:45 |

US3252127

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User entered 'I' | System | 08 Feb 2021 02:37:45 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Apr 2021 19:48:46 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 09 Mar 2021 03:31:12 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Apr 2021 19:48:46 |
| User entered '8 Mar 2021' | (b) (4), (b) (6) | 09 Mar 2021 03:31:12 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Apr 2021 19:48:46 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 09 Mar 2021 03:31:12 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User entered 'VISIT4' | System | 09 Mar 2021 03:31:12 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Apr 2021 19:48:46 |
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Mar 2021 20:58:50 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Apr 2021 19:48:46 |
| User entered empty. | (b) (4), (b) (6) | 30 Mar 2021 20:58:50 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Apr 2021 19:48:46 |
| User entered empty. | (b) (4), (b) (6) | 30 Mar 2021 20:58:50 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User entered empty. | System | 30 Mar 2021 20:58:50 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Apr 2021 19:48:46 |
| User entered empty. | (b) (4), (b) (6) | 30 Mar 2021 20:58:50 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Apr 2021 19:48:46 |
| User entered empty. | (b) (4), (b) (6) | 30 Mar 2021 20:58:50 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Apr 2021 19:48:46 |
| User entered empty. | (b) (4), (b) (6) | 30 Mar 2021 20:58:50 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Apr 2021 19:48:46 |
| User entered empty. | (b) (4), (b) (6) | 30 Mar 2021 20:58:50 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User entered empty. | System | 30 Mar 2021 20:58:50 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Apr 2021 19:48:46 |
| User entered empty. | (b) (4), (b) (6) | 30 Mar 2021 20:58:50 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User entered empty. | System | 30 Mar 2021 20:58:50 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Apr 2021 19:48:46 |
| User entered empty. | (b) (4), (b) (6) | 30 Mar 2021 20:58:50 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User entered empty. | System | 30 Mar 2021 20:58:50 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Apr 2021 19:48:46 |
| User entered empty. | (b) (4), (b) (6) | 30 Mar 2021 20:58:50 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User entered empty. | System | 30 Mar 2021 20:58:50 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| | | |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:59

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Apr 2021 19:48:46 |
| User entered 'No (N)' | (b) (4), (b) (6) | 09 Mar 2021 03:31:20 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:59

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Apr 2021 19:48:46 |
| User entered empty. | (b) (4), (b) (6) | 09 Mar 2021 03:31:20 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:59

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Apr 2021 19:48:46 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 09 Mar 2021 03:31:38 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:59

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Apr 2021 19:48:46 |
| User entered '8 Mar 2021' | (b) (4), (b) (6) | 09 Mar 2021 03:31:38 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:59

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Apr 2021 19:48:46 |
| User entered '15:26' | (b) (4), (b) (6) | 09 Mar 2021 03:31:38 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:59

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User entered '8 Mar 2021 15:26' | System | 09 Mar 2021 03:31:38 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Apr 2021 19:48:46 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 09 Mar 2021 03:31:59 |

US3252127

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:13:35 |
| User entered 'I' | System | 09 Mar 2021 03:31:59 |

US3252127

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 05:06:21 |
| User signature succeeded. | Joel Solis (b) (4) | 08 Apr 2021 02:03:57 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 07 Apr 2021 02:46:55 |

(b)

US3252127

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 05:06:21 |
| User signature succeeded. | Joel Solis (b) (4) | 08 Apr 2021 02:03:57 |
| User entered '6 Apr 2021' | (b) (4), (b) (6) | 07 Apr 2021 02:46:55 |

US3252127

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 05:06:21 |
| User signature succeeded. | Joel Solis (b) (4) | 08 Apr 2021 02:03:57 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 07 Apr 2021 02:46:55 |

US3252127

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:59

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 05:06:21 |
| User signature succeeded. | Joel Solis (b) (4) | 08 Apr 2021 02:03:57 |
| User entered empty. | (b) (4), (b) (6) | 07 Apr 2021 02:46:55 |

US3252127

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 05:06:21 |
| User signature succeeded. | Joel Solis (b) (4) | 08 Apr 2021 02:03:57 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 07 Apr 2021 02:46:46 |

US3252127

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:59

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 05:06:21 |
| User entered '1' | System | 07 Apr 2021 02:46:46 |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:09:59

[Date of Contact](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:30 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '05 Jan 2021' | Shannon Moyer (b) (4) | 06 Jan 2021 03:05:54 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:09:59

[Time of Contact](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:30 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '09:52' | Shannon Moyer (b) (4) | 06 Jan 2021 03:05:54 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:09:59

[Date and Time of Contact \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:30 |
| User entered '05 Jan 2021 09:52' | System | 06 Jan 2021 03:05:54 |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:09:59

[Type of Contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:30 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:05:54 |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:09:59

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:30 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:05:54 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:09:59

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Day 1 (Day 1)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:08:35 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:09:59

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '05 Jan 2021' | Shannon Moyer (b) (4) | 06 Jan 2021 03:08:35 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:09:59

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '0' | Shannon Moyer (b) (4) | 06 Jan 2021 03:08:35 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:09:59

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '98' | Shannon Moyer (b) (4) | 06 Jan 2021 03:08:35 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:09:59

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User entered '%' | System | 06 Jan 2021 03:08:35 |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:09:59

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '98.8' F | Shannon Moyer (b) (4) | 06 Jan 2021 03:08:35 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:09:59

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Mild (Mild)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:08:35 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:09:59

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:08:35 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:09:59

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:08:35 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:09:59

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:08:35 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:09:59

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:08:35 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:09:59

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:08:35 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:09:59

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:08:35 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:09:59

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:08:35 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:09:59

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:08:35 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:09:59

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:08:35 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:09:59

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:08:35 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:09:59

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:08:35 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:09:59

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:08:35 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:09:59

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:08:35 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:09:59

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:08:35 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:09:59

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:08:35 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:09:59

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Day 2 (Day 2)' | Shannon Moyer (b) (4) | 07 Jan 2021 06:35:04 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:09:59

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '06 Jan 2021' | Shannon Moyer (b) (4) | 07 Jan 2021 06:35:04 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:09:59

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '0' | Shannon Moyer (b) (4) | 07 Jan 2021 06:35:04 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:09:59

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '97' | Shannon Moyer (b) (4) | 07 Jan 2021 06:35:04 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:09:59

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User entered '%' | System | 07 Jan 2021 06:35:04 |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:09:59

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '97.4' F | Shannon Moyer (b) (4) | 07 Jan 2021 06:35:04 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:09:59

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Mild (Mild)' | Shannon Moyer (b) (4) | 07 Jan 2021 06:35:04 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:09:59

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 07 Jan 2021 06:35:04 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:09:59

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 07 Jan 2021 06:35:04 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:09:59

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 07 Jan 2021 06:35:04 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:09:59

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 07 Jan 2021 06:35:04 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:09:59

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 07 Jan 2021 06:35:04 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:09:59

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 07 Jan 2021 06:35:04 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:09:59

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 07 Jan 2021 06:35:04 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:09:59

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 07 Jan 2021 06:35:04 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:09:59

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 07 Jan 2021 06:35:04 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:09:59

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 07 Jan 2021 06:35:04 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:09:59

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 07 Jan 2021 06:35:04 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:09:59

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 07 Jan 2021 06:35:04 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:09:59

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 07 Jan 2021 06:35:04 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:09:59

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 07 Jan 2021 06:35:04 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:09:59

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 07 Jan 2021 06:35:04 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:09:59

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Day 3 (Day 3)' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:05 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:09:59

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '07 Jan 2021' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:05 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:09:59

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '0' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:05 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:09:59

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '99' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:05 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:09:59

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User entered '%' | System | 08 Jan 2021 06:05:05 |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:09:59

[Temperature](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 08 Jan 2021 06:05:14 |
| User entered '97' F reason for change: Data Entry Error | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:14 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 08 Jan 2021 06:05:05 |
| User entered '97' (non-conformant). | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:05 |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:09:59

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:05 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:09:59

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:05 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:09:59

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:05 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:09:59

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:05 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:09:59

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:05 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:09:59

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:05 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:09:59

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:05 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:09:59

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:05 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:09:59

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:05 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:09:59

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:05 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:09:59

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:05 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:09:59

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:05 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:09:59

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:05 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:09:59

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:05 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:09:59

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:05 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:09:59

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'None (None)' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:05 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:09:59

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Day 4 (Day 4)' | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:09:59

[Date](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '8 Jan 2021' | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:09:59

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'I' | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:09:59

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:09:59

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User entered empty. | System | 11 Jan 2021 02:51:01 |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:09:59

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:09:59

[Chills](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:09:59

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:09:59

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:09:59

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:09:59

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:09:59

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:09:59

[Body Aches](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:09:59

[Headache](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:09:59

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:09:59

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:09:59

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:09:59

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:09:59

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:09:59

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:09:59

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:09:59

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:09:59

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Day 5 (Day 5)' | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:09:59

[Date](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '9 Jan 2021' | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:09:59

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'I' | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:09:59

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:09:59

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User entered empty. | System | 11 Jan 2021 02:51:01 |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:09:59

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:09:59

[Chills](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:09:59

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:09:59

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:09:59

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:09:59

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:09:59

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:09:59

[Body Aches](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:09:59

[Headache](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:09:59

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:09:59

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:09:59

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:09:59

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:09:59

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:09:59

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:09:59

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:09:59

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 11 Jan 2021 02:51:01 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:09:59

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Day 6 (Day 6)' | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:09:59

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '10 Jan 2021' | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:09:59

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '1' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:49 |
| User entered '0' | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:09:59

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:09:59

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User entered empty. | System | 12 Jan 2021 02:39:41 |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:09:59

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:09:59

[Chills](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:09:59

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:09:59

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:09:59

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:09:59

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:09:59

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:09:59

[Body Aches](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:09:59

[Headache](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:09:59

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:09:59

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:09:59

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:09:59

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:09:59

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:09:59

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:09:59

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:09:59

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:09:59

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Day 7 (Day 7)' | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:09:59

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '11 Jan 2021' | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:09:59

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '1' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:49 |
| User entered '0' | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:09:59

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:09:59

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User entered empty. | System | 12 Jan 2021 02:39:41 |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:09:59

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:09:59

[Chills](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:09:59

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:09:59

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:09:59

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:09:59

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:09:59

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:09:59

[Body Aches](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:09:59

[Headache](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:09:59

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:09:59

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:09:59

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:09:59

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:09:59

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:09:59

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:09:59

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:09:59

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:36 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 12 Jan 2021 02:39:41 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:09:59

[Date of Visit](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:40 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 05JAN2021 is recorded under Covid-19 Assessment in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). | (b) (4), (b) (6) | 11 Feb 2021 09:15:09 |
| Query 'Per GCL Lab Reconciliation: Swab: Sample dated 05JAN2021 is recorded under Covid-19 Assessment in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Patients PCR COVID-19 results came back negative on 1/12/21. accession number not available' (Site from DM). | Shannon Moyer (b) (4) (b) (4) | 08 Feb 2021 06:41:25 |
| User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 05JAN2021 is recorded under Covid-19 Assessment in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). | (b) (4), (b) (6) | 13 Jan 2021 11:56:52 |
| User entered '05 Jan 2021' | Shannon Moyer (b) (4) (b) (4) | 06 Jan 2021 03:09:14 |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:09:59

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:40 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:09:14 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:09:59

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:40 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 08 Feb 2021 06:40:20 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 08 Feb 2021 06:40:20 |
| User entered 'No (N)' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 08 Feb 2021 06:40:20 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 06 Jan 2021 03:09:14 |
| User entered empty. | Shannon Moyer (b) (4) | 06 Jan 2021 03:09:14 |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:09:59

[Date of Test](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:40 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '05 Jan 2021' | Shannon Moyer (b) (4) | 06 Jan 2021 03:09:14 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:09:59

[Type of Test Performed](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:40 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:09:14 |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:09:59

[Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:40 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 06 Jan 2021 03:09:14 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:09:59

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:40 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:09:14 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:09:59

[Lab/ Institution Test Performed](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:40 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 06 Jan 2021 03:09:14 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:09:59

[CLIA Certified?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:40 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 06 Jan 2021 03:09:14 |
| | (b) (4) | |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:09:59

[COVID-19 Positive \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:40 |
| User entered '0' | System | 08 Feb 2021 06:40:20 |

US3252127

Folder: Covid-19 Assessment 05 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:09:59

[Generate Next COVID-19 Assessment](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:41:45 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:09:26 |
| | (b) (4) | |

US3252127

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:09:59

[Visit](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User accepted default value 'Day 3 (Day 3)' | Shannon Moyer (b) (4) (b) (4) | 08 Jan 2021 06:05:34 |

US3252127

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:09:59

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 22 Apr 2021 18:47:25 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:34 |
| | (b) (4) | |

US3252127

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:09:59

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 22 Apr 2021 18:47:25 |
| User closed query 'Per GCL LAB reconciliation: Saliva: Sample dated 07JAN2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM). | (b) (4), (b) (6) | 08 Apr 2021 05:50:23 |
| Query 'Per GCL LAB reconciliation: Saliva: Sample dated 07JAN2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' | (b) (4), (b) (6) | 07 Apr 2021 05:19:41 |
| answered with 'Accession # and Tracking number - 9394 7432 8866 and the shipment date is 04-Feb -2021' (Site from DM). | | |
| User opened query 'Per GCL LAB reconciliation: Saliva: Sample dated 07JAN2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM). | (b) (4), (b) (6) | 10 Feb 2021 05:31:02 |
| User entered '07 Jan 2021' | Shannon Moyer (b) (4) (b) (4) | 08 Jan 2021 06:05:34 |

US3252127

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:09:59

[Visit](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User accepted default value 'Day 5 (Day 5)' | Shannon Moyer (b) (4) (b) (4) | 08 Jan 2021 06:05:34 |

US3252127

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:09:59

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 22 Apr 2021 18:47:25 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 12 Jan 2021 02:40:36 |
| User entered 'No (N)' | (b) (4) | |
| | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:34 |
| | (b) (4) | |

US3252127

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:09:59

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 22 Apr 2021 18:47:25 |
| User closed query 'Per GCL Lab Reconciliation: Saliva : For Day 5, EDC Sample date is 09JAN2021, however in PPD Central Lab sample dated 07JAN2021(Accession # 1F650389598) is reported. Hence please review this Accession number to confirm correct date of collection for Day 5 and update EDC or PPD Central lab.' (Site from DM). | (b) (4), (b) (6) | 16 Apr 2021 06:25:42 |
| Query 'Per GCL Lab Reconciliation: Saliva : For Day 5, EDC Sample date is 09JAN2021, however in PPD Central Lab sample dated 07JAN2021(Accession # 1F650389598) is reported. Hence please review this Accession number to confirm correct date of collection for Day 5 and update EDC or PPD Central lab.' answered with 'The collection date is generalized for the start of D3 illness visit due to the requisition form containing saliva samples D3-D21' (Site from DM). | (b) (4), (b) (6) | 12 Apr 2021 09:07:51 |
| User opened query 'Per GCL Lab Reconciliation: Saliva : For Day 5, EDC Sample date is 09JAN2021, however in PPD Central Lab sample dated 07JAN2021(Accession # 1F650389598) is reported. Hence please review this Accession number to confirm correct date of collection for Day 5 and update EDC or PPD Central lab.' (Site from DM). | (b) (4), (b) (6) | 09 Apr 2021 10:04:43 |
| User closed query 'Per GCL LAB reconciliation: Saliva: Sample dated 09JAN2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you. (Site from DM). | (b) (4), (b) (6) | 09 Apr 2021 10:01:55 |
| Query 'Per GCL LAB reconciliation: Saliva: Sample dated 09JAN2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you. ' answered with 'the Accession number is 9394 7432 8866 and the shipping date is 04-FEB-2021' (Site from DM). | (b) (4), (b) (6) | 09 Apr 2021 03:51:11 |
| User entered '09 Jan 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 08 Apr 2021 04:30:16 |

US3252127

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:09:59

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User opened query 'Per GCL LAB reconciliation: Saliva: Sample dated 09JAN2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 10 Feb 2021 05:42:45 |
| User entered '9 Jan 2021' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 12 Jan 2021 02:40:36 |
| User entered empty. | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:34 |

US3252127

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:09:59

[Visit](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User accepted default value 'Day 7 (Day 7)' | Shannon Moyer (b) (4) (b) (4) | 08 Jan 2021 06:05:34 |

US3252127

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:09:59

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 22 Apr 2021 18:47:25 |
| User entered 'No (N)' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:34 |
| | (b) (4) | |

US3252127

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:09:59

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 22 Apr 2021 18:47:25 |
| User entered empty. | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:34 |
| | (b) (4) | |

US3252127

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:09:59

[Visit](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User accepted default value 'Day 9 (Day 9)' | Shannon Moyer (b) (4) (b) (4) | 08 Jan 2021 06:05:34 |

US3252127

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:09:59

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 22 Apr 2021 18:47:25 |
| User entered 'No (N)' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:34 |
| | (b) (4) | |

US3252127

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:09:59

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 22 Apr 2021 18:47:25 |
| User entered empty. | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:34 |
| | (b) (4) | |

US3252127

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:09:59

[Visit](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User accepted default value 'Day 14 (Day 14)' | Shannon Moyer (b) (4) (b) (4) | 08 Jan 2021 06:05:34 |

US3252127

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:09:59

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 22 Apr 2021 18:47:25 |
| User entered 'No (N)' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:34 |
| | (b) (4) | |

US3252127

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:09:59

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 22 Apr 2021 18:47:25 |
| User entered empty. | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:34 |
| | (b) (4) | |

US3252127

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:09:59

[Visit](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User accepted default value 'Day 21 (Day 21)' | Shannon Moyer (b) (4) (b) (4) | 08 Jan 2021 06:05:34 |

US3252127

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:09:59

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 22 Apr 2021 18:47:25 |
| User entered 'No (N)' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:34 |
| | (b) (4) | |

US3252127

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:09:59

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 22 Apr 2021 18:47:25 |
| User entered empty. | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:34 |
| | (b) (4) | |

US3252127

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:09:59

[Visit](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User accepted default value 'Day 28 (Day 28)' | Shannon Moyer (b) (4) (b) (4) | 08 Jan 2021 06:05:34 |

US3252127

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:09:59

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 22 Apr 2021 18:47:25 |
| User entered 'No (N)' | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:34 |
| | (b) (4) | |

US3252127

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:09:59

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 22 Apr 2021 18:47:25 |
| User entered empty. | Shannon Moyer (b) (4) | 08 Jan 2021 06:05:34 |
| | (b) (4) | |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:09:41 |
| | (b) (4) | |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '05 Jan 2021' | Shannon Moyer (b) (4) | 06 Jan 2021 03:09:41 |
| | (b) (4) | |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Clinic (Clinic)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:09:41 |
| | (b) (4) | |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| User entered 'SICKD1' | System | 06 Jan 2021 03:09:41 |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:10:22 |
| | (b) (4) | |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '05 Jan 2021' | Shannon Moyer (b) (4) | 06 Jan 2021 03:10:22 |
| | (b) (4) | |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '09:44' | Shannon Moyer (b) (4) | 06 Jan 2021 03:10:22 |
| | (b) (4) | |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| User entered '05 Jan 2021 09:44' | System | 06 Jan 2021 03:10:22 |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Height \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 08 Feb 2021 04:53:07 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System | 08 Feb 2021 04:53:07 |
| User entered '68.7' in reason for change: Data Entry Error | Shannon Moyer (b) (4) | 08 Feb 2021 04:53:07 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 06 Jan 2021 03:10:22 |
| User entered empty. | Shannon Moyer (b) (4) | 06 Jan 2021 03:10:22 |
| DataPoint set to visible. | System | 06 Jan 2021 03:09:41 |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

Weight (xxx.x)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 08 Feb 2021 04:53:07 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System | 08 Feb 2021 04:53:07 |
| User entered '199' lb reason for change: Data Entry Error | Shannon Moyer (b) (4) | 08 Feb 2021 04:53:07 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 06 Jan 2021 03:10:22 |
| User entered empty. | Shannon Moyer (b) (4) | 06 Jan 2021 03:10:22 |
| DataPoint set to visible. | System | 06 Jan 2021 03:09:41 |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '98.8' F | Shannon Moyer (b) (4) | 06 Jan 2021 03:10:22 |
| | (b) (4) | |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Oral (Oral)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:10:22 |
| | (b) (4) | |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 06 Jan 2021 03:10:22 |
| | (b) (4) | |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '76' | Shannon Moyer (b) (4) | 06 Jan 2021 03:10:22 |
| | (b) (4) | |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| User entered 'bpm' | System | 06 Jan 2021 03:10:22 |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '15' | Shannon Moyer (b) (4) | 06 Jan 2021 03:10:22 |
| | (b) (4) | |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| User entered 'breaths/min' | System | 06 Jan 2021 03:10:22 |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '129' | Shannon Moyer (b) (4) | 06 Jan 2021 03:10:22 |
| | (b) (4) | |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| User entered 'mmHg' | System | 06 Jan 2021 03:10:22 |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '75' | Shannon Moyer (b) (4) | 06 Jan 2021 03:10:22 |
| | (b) (4) | |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| User entered 'mmHg' | System | 06 Jan 2021 03:10:22 |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

Height (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| | | |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:59

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| | | |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:59

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:10:55 |
| | (b) (4) | |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:59

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '05 Jan 2021' | Shannon Moyer (b) (4) | 06 Jan 2021 03:10:55 |
| | (b) (4) | |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:09:59

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 06 Jan 2021 03:12:25 |
| | (b) (4) | |

US3252127

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:09:59

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 19:37:05 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '05 Jan 2021' | Shannon Moyer (b) (4) | 06 Jan 2021 03:12:25 |
| | (b) (4) | |

US3252127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:30:28 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 23 Jan 2021 05:52:01 |
| | (b) (4) | |

US3252127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:30:28 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '22 Jan 2021' | Shannon Moyer (b) (4) | 23 Jan 2021 05:52:01 |
| | (b) (4) | |

US3252127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:30:28 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Clinic (Clinic)' | Shannon Moyer (b) (4) | 23 Jan 2021 05:52:01 |
| | (b) (4) | |

US3252127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:59

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:30:28 |
| User entered 'UNBLND_DECIDE' | System | 23 Jan 2021 05:52:01 |

US3252127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:09:59

Date of updated informed consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:30:28 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '22 Jan 2021' | Shannon Moyer (b) (4) | 23 Jan 2021 05:52:20 |
| | (b) (4) | |

US3252127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:09:59

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:30:28 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Apr 2021 19:48:46 |
| User entered '0' WR# 5295537 | System | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 03:54:40 |

US3252127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:09:59

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:30:28 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 23 Jan 2021 05:52:20 |
| | (b) (4) | |

US3252127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:09:59

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:30:28 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Apr 2021 19:48:46 |
| User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537 | System | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 03:54:40 |

US3252127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:09:59

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:30:28 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '22 Jan 2021' | Shannon Moyer (b) (4) | 23 Jan 2021 05:52:20 |
| | (b) (4) | |

US3252127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:09:59

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:30:28 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'mRNA-1273 (mRNA-1273)' | Shannon Moyer (b) (4) | 23 Jan 2021 05:52:20 |
| | (b) (4) | |

US3252127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:09:59

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:30:28 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'mRNA-1273 (mRNA-1273)' | Shannon Moyer (b) (4) | 23 Jan 2021 05:52:20 |
| | (b) (4) | |

US3252127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:09:59

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:30:28 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'mRNA-1273 (mRNA-1273)' | Shannon Moyer (b) (4) | 23 Jan 2021 05:52:20 |
| | (b) (4) | |

US3252127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:09:59

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:30:28 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Shannon Moyer (b) (4) | 23 Jan 2021 05:52:20 |
| | (b) (4) | |

US3252127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:09:59

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:30:28 |
| User entered empty. | System | 23 Jan 2021 05:52:20 |

US3252127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:09:59

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:30:28 |
| User entered empty. | System | 23 Jan 2021 05:52:20 |

US3252127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:59

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:30:28 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 23 Jan 2021 05:52:34 |
| | (b) (4) | |

US3252127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:59

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:30:28 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '22 Jan 2021' | Shannon Moyer (b) (4) | 23 Jan 2021 05:52:34 |
| | (b) (4) | |

US3252127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:59

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:30:28 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '11:40' reason for change: Data Entry | Shannon Moyer (b) (4) | 23 Jan 2021 05:53:08 |
| Error | (b) (4) | |
| User entered '11:08' | Shannon Moyer (b) (4) | 23 Jan 2021 05:52:34 |
| | (b) (4) | |

US3252127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:59

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:30:28 |
| User entered '22 Jan 2021 11:40' | System | 23 Jan 2021 05:53:08 |
| User entered '22 Jan 2021 11:08' | System | 23 Jan 2021 05:52:34 |

US3252127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:09:59

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:30:28 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 23 Jan 2021 05:53:16 |
| | (b) (4) | |

US3252127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:09:59

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:30:28 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '22 Jan 2021' | Shannon Moyer (b) (4) | 23 Jan 2021 05:53:16 |
| | (b) (4) | |

US3252127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:09:59

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:30:28 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '11:40' | Shannon Moyer (b) (4) | 23 Jan 2021 05:53:16 |
| | (b) (4) | |

US3252127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:09:59

[Collection Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:30:28 |
| User entered '22 Jan 2021 11:40' | System | 23 Jan 2021 05:53:16 |

US3252127

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:09:59

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 04:40:41 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:39 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Oct 2020 20:54:06 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:51:23 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[AEID](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Dec 2020 18:11:16 |
| Un-reviewed for Safety. | | 05 Dec 2020 18:11:02 |
| Reviewed for Safety. | | 05 Dec 2020 18:09:41 |
| DataPoint Verified. | | 20 Nov 2020 20:31:58 |
| User entered 'USA-US108-2020-mRNA-1273-P301000013' | System | 04 Nov 2020 17:47:49 |
| User entered 'New' | (b) (4), (b) (6) | 04 Nov 2020 17:47:49 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:32:00 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 03 Nov 2020 22:48:26 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 03 Nov 2020 22:48:26 |
| Data point term sent to Coder | System | 03 Nov 2020 22:47:42 |
| User entered 'Appendicitis' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:32:06 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:32:09 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:42:08 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:42:11 |
| User entered '28 Oct 2020' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Dec 2020 01:04:25 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 21:11:42 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

If not Ongoing, end date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 21:11:39 |
| User entered '29 Oct 2020' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 21:11:49 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

Severity

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:18:39 |
| User closed query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety). | (b) (4), (b) (6) | 05 Dec 2020 18:08:28 |
| Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' answered with 'UPDATED.' (Site from Safety). | Joanna Gurrola Mahoney (b) (4) | 04 Dec 2020 20:53:14 |
| DataPoint Un-verified. | Joanna Gurrola Mahoney (b) (4) | 04 Dec 2020 20:52:57 |
| User entered 'Grade 4 (Grade 4)' reason for change: | Joanna Gurrola Mahoney (b) (4) | 04 Dec 2020 20:52:57 |
| Data Entry Error | (b) (4) | |
| User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety). | (b) (4), (b) (6) | 01 Dec 2020 14:24:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 21:12:22 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 21:12:29 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

Death

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 21:12:36 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 21:12:37 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | System | 21 Nov 2020 15:58:02 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System). | System | 21 Nov 2020 15:58:02 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | System | 21 Nov 2020 15:30:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 21:12:34 |
| User entered '1' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Dec 2020 01:04:43 |
| | | |
| User entered '28 Oct 2020' reason for change: Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 21 Nov 2020 15:58:02 |
| User entered empty; reason for change Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 21 Nov 2020 15:30:50 |
| User entered '28 Oct 2020' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Dec 2020 01:04:44 |
| | | |
| User entered '29 Oct 2020' reason for change: Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 21 Nov 2020 15:58:02 |
| User entered empty; reason for change Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 21 Nov 2020 15:30:50 |
| User entered '29 Oct 2020' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Dec 2020 01:04:46 |
| DataPoint Un-verified. | | 20 Nov 2020 22:17:20 |
| DataPoint Verified. | | 20 Nov 2020 22:17:17 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Dec 2020 01:04:47 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 22:20:25 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 22:20:26 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 22:20:27 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Dec 2020 01:10:48 |
| User entered 'Not Related (NOT RELATED)' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 22:20:49 |
| User entered 'Not Related (NOT RELATED)' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

Action taken with investigational product

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Dec 2020 01:05:36 |
| User closed query 'PV Query: As the last dose of study drug was given on 08 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety). | (b) (4), (b) (6) | 23 Nov 2020 20:26:52 |
| Query 'PV Query: As the last dose of study drug was given on 08 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated.' (Site from Safety). | Joanna Gurrola Mahoney (b) (4) | 21 Nov 2020 15:47:39 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 21 Nov 2020 15:44:09 |
| User opened query 'PV Query: As the last dose of study drug was given on 08 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety). | (b) (4), (b) (6) | 13 Nov 2020 16:15:07 |
| User entered 'None (NONE)' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

None

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 21:43:02 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 21:43:03 |
| User entered 'I' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 21:43:05 |
| User entered 'I' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[Outcome](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 21:43:07 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 21:43:11 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[Narrative](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User closed query 'Per source, medical records are uploaded to source. Please send to Safety_Moderna@iqvia.com of fax in. ' (Site from CRA). | (b) (4), (b) (6) | 19 Mar 2021 17:57:47 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| Query 'Per source, medical records are uploaded to source. Please send to Safety_Moderna@iqvia.com of fax in. ' answered with 'Records were sent on 1/13/21.' (Site from CRA). | mathew maran (b) (4) | 01 Mar 2021 10:14:15 |
| User opened query 'Per source, medical records are uploaded to source. Please send to Safety_Moderna@iqvia.com of fax in. ' (Site from CRA). | (b) (4) | |
| User opened query 'Per source, medical records are uploaded to source. Please send to Safety_Moderna@iqvia.com of fax in. ' (Site from CRA). | (b) (4), (b) (6) | 09 Feb 2021 16:52:18 |
| 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 Feb 2021 16:15:07 |
| 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 'unable to obtain' (Site from Safety). | Shannon Moyer (b) (4) | 04 Feb 2021 06:25:42 |
| 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) | 07 Jan 2021 16:12:50 |
| 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).' (Site from Safety). | (b) (4), (b) (6) | 07 Jan 2021 16:12:44 |
| 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) | 07 Jan 2021 16:12:39 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[Narrative](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'no data obtained' (Site from Safety). | Shannon Moyer (b) (4) | 06 Jan 2021 03:16:27 |
| 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).' answered with 'patient got surgery on 28th October 2020' (Site from Safety). | Shannon Moyer (b) (4) | 06 Jan 2021 03:16:12 |
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'no data obtained' (Site from Safety). | Shannon Moyer (b) (4) | 06 Jan 2021 03:15:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Dec 2020 01:06:09 |
| User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety). | (b) (4), (b) (6) | 13 Nov 2020 16:15:42 |
| 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).' (Site from Safety). | (b) (4), (b) (6) | 13 Nov 2020 16:15:27 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 13 Nov 2020 16:15:18 |
| 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) | 13 Nov 2020 16:14:55 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[Narrative](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User entered 'Patient presented with appendicitis on October 28th, got operated the same day and got discharged on October 29th.' | Joanna Gurrola Mahoney (b) (4) | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Nov 2020 22:47:07 |

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 03 Nov 2020 22:47:07 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:09:59

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 04:40:41 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Dec 2020 01:11:44 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:51:57 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: FENOFIBRATE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 14 Aug 2020 00:20:11 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 14 Aug 2020 00:20:11 |
| Data point term sent to Coder | System | 12 Aug 2020 19:55:56 |
| User entered 'Fenofiberate' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:55:24 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:55:24 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:59

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Hypercholesteremia' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:55:24 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '134' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:55:24 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'mg (mg)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:55:24 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:55:24 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'once daily (QD)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:55:24 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:55:24 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Oral (ORAL)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:55:24 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:55:24 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 13 Aug 2020 11:19:32 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 12 Aug 2020 19:55:24 |
| User entered 'UN UNK 2010' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:55:24 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:55:24 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:55:24 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:55:24 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:55:24 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Aug 2020 19:55:24 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Aug 2020 19:55:24 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 12 Aug 2020 19:55:24 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 28 Sep 2020 21:06:53 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 28 Sep 2020 21:06:53 |
| Data point term sent to Coder | System | 28 Sep 2020 21:06:08 |
| Coding entries removed. | (b) (4), (b) (6) | 28 Sep 2020 21:05:48 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 13 Aug 2020 12:59:24 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 13 Aug 2020 12:59:24 |
| Data point term sent to Coder | System | 12 Aug 2020 19:57:59 |
| User entered 'Montelukast' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:57:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:57:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:59

[Indication](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Asthma' reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Sep 2020 21:05:48 |
| User entered 'Sinusitis' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:57:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '10' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:57:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'mg (mg)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:57:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:57:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'once daily (QD)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:57:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:57:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Oral (ORAL)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:57:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:57:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User closed query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH record. Please reconcile and update applicable details as appropriate. Otherwise, clarify. (Site from DM). | (b) (4), (b) (6) | 27 Oct 2020 14:09:17 |
| Query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH record. Please reconcile and update applicable details as appropriate. Otherwise, clarify. (Site from DM). | (b) (4), (b) (6) | 28 Sep 2020 21:06:11 |
| User opened query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH record. Please reconcile and update applicable details as appropriate. Otherwise, clarify. (Site from DM). | (b) (4), (b) (6) | 14 Sep 2020 08:03:02 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile. canceled (Site from System). | (b) (4), (b) (6) | 13 Aug 2020 11:19:37 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 12 Aug 2020 19:57:20 |
| User entered 'UN UNK 2010' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:57:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:57:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:57:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:57:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 19:57:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Aug 2020 19:57:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Aug 2020 19:57:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 12 Aug 2020 19:57:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 13 Aug 2020 12:04:48 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 13 Aug 2020 12:04:48 |
| Data point term sent to Coder | System | 12 Aug 2020 20:02:15 |
| User entered 'Pravastatin' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:01:48 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:01:48 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:59

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Hypercholesterol' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:01:48 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '20' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:01:48 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'mg (mg)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:01:48 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:01:48 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'once daily (QD)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:01:48 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:01:48 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Oral (ORAL)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:01:48 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:01:48 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6) | 13 Aug 2020 11:19:41 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Per source correct as is.' (Site from System). | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:02:59 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 12 Aug 2020 20:01:48 |
| User entered 'UN UNK 2010' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:01:48 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:01:48 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:01:48 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:01:48 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:01:48 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Aug 2020 20:01:48 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Aug 2020 20:01:48 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 12 Aug 2020 20:01:48 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:59

Name of Medication

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: DOXAZOSIN MESILATE, PRODUCTSYNONYM: DOXAZOSIN MESYLATE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 14 Aug 2020 00:06:16 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 14 Aug 2020 00:06:16 |
| Data point term sent to Coder | System | 12 Aug 2020 20:06:26 |
| User entered 'Doxazosin mesylate' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:05:30 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:05:30 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:59

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Hypertension' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:05:30 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '4' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:05:30 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'mg (mg)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:05:30 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:05:30 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:59

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'twice daily (BID)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:05:30 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:05:30 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Oral (ORAL)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:05:30 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:05:30 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 13 Aug 2020 11:19:45 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 12 Aug 2020 20:05:30 |
| User entered 'UN UNK 2018' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:05:30 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:05:30 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:05:30 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:05:30 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:05:30 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 12 Aug 2020 20:05:30 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Aug 2020 20:05:30 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 12 Aug 2020 20:05:30 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Aug 2020 20:08:11 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Aug 2020 20:08:11 |
| Data point term sent to Coder | System | 12 Aug 2020 20:07:29 |
| User entered 'Metoprolol' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:07:07 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:07:07 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:59

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Hypertension' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:07:07 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '50' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:07:07 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'mg (mg)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:07:07 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:07:07 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:59

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'twice daily (BID)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:07:07 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:07:07 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Oral (ORAL)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:07:07 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:07:07 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 13 Aug 2020 11:19:50 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 12 Aug 2020 20:07:07 |
| User entered 'UN UNK 2010' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:07:07 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:07:07 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:07:07 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:07:07 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:07:07 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 12 Aug 2020 20:07:07 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Aug 2020 20:07:07 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 12 Aug 2020 20:07:07 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User coded data point as ATC: | Coder Import (b) (4) | 12 Aug 2020 20:10:12 |
| 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. | (b) (4) | |
| User coded data point as Term Coded data point by | Coder Import (b) (4) | 12 Aug 2020 20:10:12 |
| User: Coder System - version WHODrug-Global-B3\202003. | (b) (4) | |
| Data point term sent to Coder | System | 12 Aug 2020 20:09:34 |
| User entered 'Amlodipine' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:08:40 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:08:40 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:59

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Hypertension' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:08:40 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '5' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:08:40 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'mg (mg)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:08:40 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:08:40 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:59

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'twice daily (BID)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:08:40 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:08:40 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Oral (ORAL)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:08:40 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:08:40 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 13 Aug 2020 11:19:54 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 12 Aug 2020 20:08:40 |
| User entered 'UN UNK 2010' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:08:40 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:08:40 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:08:40 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:08:40 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:08:40 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 12 Aug 2020 20:08:40 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Aug 2020 20:08:40 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 12 Aug 2020 20:08:40 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 14 Aug 2020 00:23:10 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 14 Aug 2020 00:23:10 |
| Data point term sent to Coder | System | 12 Aug 2020 20:10:38 |
| User entered 'Finisteride' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:10:19 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:10:19 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:59

[Indication](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Enlarged Prostate' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:10:19 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '5' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:10:19 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'mg (mg)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:10:19 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:10:19 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'every other day (QOD)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:10:19 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:10:19 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Oral (ORAL)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:10:19 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:10:19 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 13 Aug 2020 11:19:58 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 12 Aug 2020 20:10:19 |
| User entered 'UN UNK 2009' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:10:19 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:10:19 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:10:19 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:10:19 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:10:19 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Aug 2020 20:10:19 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 12 Aug 2020 20:10:19 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 12 Aug 2020 20:10:19 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:59

Name of Medication

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 28 Sep 2020 23:09:42 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 28 Sep 2020 23:09:42 |
| Data point term sent to Coder | System | 28 Sep 2020 21:07:11 |
| Coding entries removed. | (b) (4), (b) (6) | 28 Sep 2020 21:06:55 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 14 Aug 2020 00:00:19 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 14 Aug 2020 00:00:19 |
| Data point term sent to Coder | System | 12 Aug 2020 20:14:52 |
| User entered 'Diclofenac 1% topical gel' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:14:10 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:14:10 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:59

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User closed query 'Per DM CLR: Please review Indication and please update to specify the location of Osteoarthritis. Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 22 Oct 2020 22:42:57 |
| Query 'Per DM CLR: Please review Indication and please update to specify the location of Osteoarthritis. Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify.' answered with 'HANDS' (Site from DM). | (b) (4), (b) (6) | 28 Sep 2020 21:07:00 |
| User entered 'OSTEOARTHRITIS OF HANDS' reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Sep 2020 21:06:55 |
| User opened query 'Per DM CLR: Please review Indication and please update to specify the location of Osteoarthritis. Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 13 Sep 2020 09:54:13 |
| User entered 'Osteoarthritis' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:14:10 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User closed query 'Per DM CLR: Please review recorded Dose and Unit as these are not expected for this medication. Please verify if the number of Application would better represent the dose and unit or this topical medication. Please update applicable details as appropriate or provide clarification.' (Site from DM). | (b) (4), (b) (6) | 22 Oct 2020 22:43:00 |
| Query 'Per DM CLR: Please review recorded Dose and Unit as these are not expected for this medication. Please verify if the number of Application would better represent the dose and unit or this topical medication. Please update applicable details as appropriate or provide clarification.' answered with 'Medical History updated.' (Site from DM). | (b) (4), (b) (6) | 28 Sep 2020 21:22:28 |
| User opened query 'Per DM CLR: Please review recorded Dose and Unit as these are not expected for this medication. Please verify if the number of Application would better represent the dose and unit or this topical medication. Please update applicable details as appropriate or provide clarification.' (Site from DM). | (b) (4), (b) (6) | 13 Sep 2020 09:54:31 |
| User entered '2' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:14:10 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Other (OTHER)' reason for change: | (b) (4), (b) (6) | 28 Sep 2020 21:10:08 |
| Data Entry Error | | |
| User entered 'g (g)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:14:10 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'applications' reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Sep 2020 21:10:08 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:14:10 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'as needed (PRN)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:14:10 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:14:10 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Topical (TOPICAL)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:14:10 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:14:10 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 13 Aug 2020 11:20:02 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 12 Aug 2020 20:14:10 |
| User entered 'UN UNK 2010' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:14:10 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:14:10 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:14:10 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:14:10 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:14:10 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 12 Aug 2020 20:14:10 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 12 Aug 2020 20:14:10 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 12 Aug 2020 20:14:10 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OTHER DRUGS FOR CONSTIPATION, PRODUCT: LINACLOTIDE, PRODUCTSYNONYM: LINZESS - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Aug 2020 20:20:09 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Aug 2020 20:20:09 |
| Data point term sent to Coder | System | 12 Aug 2020 20:19:04 |
| User entered 'Linzess' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:18:13 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:18:13 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:59

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Constipation' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:18:13 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '72' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:18:13 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Other (OTHER)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:18:13 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'mcg' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:18:13 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'once daily (QD)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:18:13 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:18:13 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Oral (ORAL)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:18:13 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:18:13 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User closed query ' | (b) (4), (b) (6) | 26 Oct 2020 19:19:34 |
| Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH record. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM). | | |
| Query ' | (b) (4), (b) (6) | 28 Sep 2020 21:24:18 |
| Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH record. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' answered with 'updated. ' (Site from DM). | | |
| User entered 'UN UNK 2019' reason for change: | (b) (4), (b) (6) | 28 Sep 2020 21:24:11 |
| Data Entry Error | | |
| User opened query ' | (b) (4), (b) (6) | 14 Sep 2020 06:40:50 |
| Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH record. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM). | | |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 13 Aug 2020 11:20:06 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 12 Aug 2020 20:18:13 |
| User entered 'UN UNK 2018' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:18:13 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:18:13 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:18:13 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:18:13 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:18:13 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Aug 2020 20:18:13 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Aug 2020 20:18:13 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 12 Aug 2020 20:18:13 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE PROPIONATE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 14 Aug 2020 00:31:11 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 14 Aug 2020 00:31:11 |
| Data point term sent to Coder | System | 12 Aug 2020 20:22:14 |
| User entered 'Fluticasone Propionate' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:21:43 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:21:43 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:59

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Asthma' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:21:43 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 29 Jan 2021 09:46:16 |
| Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'updated thanks' (Site from DM). | Shannon Moyer (b) (4) | 27 Jan 2021 11:14:23 |
| User entered '50' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 27 Jan 2021 11:14:04 |
| User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 23 Dec 2020 18:06:45 |
| User entered '1' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:21:43 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User closed query 'Per CDM: Please review the dose unit of this medication as this is not the expected dose unit (50 puff), kindly select an appropriate "Dose unit" option from the drop-down list options and update eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 09 Feb 2021 10:02:51 |
| Query 'Per CDM: Please review the dose unit of this medication as this is not the expected dose unit (50 puff), kindly select an appropriate "Dose unit" option from the drop-down list options and update eCRF as appropriate.' answered with 'updated' (Site from DM). | Shannon Moyer (b) (4) | 08 Feb 2021 05:22:20 |
| User entered 'Other (OTHER)' reason for change: Data Entry Error | (b) (4) | 08 Feb 2021 05:22:04 |
| User opened query 'Per CDM: Please review the dose unit of this medication as this is not the expected dose unit (50 puff), kindly select an appropriate "Dose unit" option from the drop-down list options and update eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 29 Jan 2021 09:47:50 |
| User entered 'puff (PUFF)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:21:43 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'mcg' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 08 Feb 2021 05:22:04 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:21:43 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:59

[Frequency](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'as needed (PRN)' reason for change: | Nancy Torrence (b) (4) | 04 Nov 2020 13:47:39 |
| Data Entry Error | (b) (4) | |
| User entered 'once daily (QD)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:21:43 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:21:43 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:21:43 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:21:43 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 13 Aug 2020 11:20:11 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 12 Aug 2020 20:21:43 |
| User entered 'UN UNK 2010' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:21:43 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:21:43 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:21:43 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:21:43 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:21:43 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Nov 2020 13:47:39 |
| User entered '1' | System | 12 Aug 2020 20:21:43 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Nov 2020 13:47:39 |
| User entered '1' | System | 12 Aug 2020 20:21:43 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered empty. | System | 04 Nov 2020 13:47:39 |
| User entered '804 (804)' | System | 12 Aug 2020 20:21:43 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Aug 2020 20:25:10 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Aug 2020 20:25:10 |
| Data point term sent to Coder | System | 12 Aug 2020 20:24:18 |
| User entered 'Zolpidem' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:23:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:23:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:59

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Insomnia' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:23:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '10' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:23:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'mg (mg)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:23:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:23:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'once daily (QD)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:23:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:23:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Oral (ORAL)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:23:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:23:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 13 Aug 2020 11:20:15 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 12 Aug 2020 20:23:20 |
| User entered 'UN UNK 2010' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:23:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:23:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:23:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:23:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:23:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Aug 2020 20:23:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Aug 2020 20:23:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 12 Aug 2020 20:23:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: EUTHYROX - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Aug 2020 20:27:10 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Aug 2020 20:27:10 |
| Data point term sent to Coder | System | 12 Aug 2020 20:26:23 |
| User entered 'Euthyrox' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:25:25 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:25:25 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:59

[Indication](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Hypothyroid' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:25:25 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '50' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:25:25 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Other (OTHER)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:25:25 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'mcg' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:25:25 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'once daily (QD)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:25:25 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:25:25 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Oral (ORAL)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:25:25 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:25:25 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 13 Aug 2020 11:20:18 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 12 Aug 2020 20:25:25 |
| User entered 'UN UNK 2019' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:25:25 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:25:25 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:25:25 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:25:25 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:25:25 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Aug 2020 20:25:25 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Aug 2020 20:25:25 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 12 Aug 2020 20:25:25 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 14 Aug 2020 07:17:21 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 14 Aug 2020 07:17:21 |
| Data point term sent to Coder | System | 12 Aug 2020 20:28:29 |
| User entered 'Multivitamins' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:27:46 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:27:46 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:59

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Dietary Supplement' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:27:46 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '1' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:27:46 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'tablet (TABLET)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:27:46 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:27:46 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'once daily (QD)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:27:46 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:27:46 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Oral (ORAL)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:27:46 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:27:46 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 13 Aug 2020 11:20:22 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 12 Aug 2020 20:27:46 |
| User entered 'UN UNK 2009' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:27:46 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:27:46 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:27:46 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:27:46 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:27:46 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Aug 2020 20:27:46 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Aug 2020 20:27:46 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 12 Aug 2020 20:27:46 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:09:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| 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) | 03 Nov 2020 13:48:19 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 03 Nov 2020 13:48:19 |
| Data point term sent to Coder | System | 02 Nov 2020 20:30:39 |
| Coding entries removed. | Joanna Gurrola Mahoney | 02 Nov 2020 20:30:26 |
| Query 'Per MM: Please recode to B01AC' canceled (Site from DM). | (b) (4) | |
| User opened query 'Per MM: Please recode to B01AC' (Site from DM). | (b) (4), (b) (6) | 23 Oct 2020 21:47:27 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003. | (b) (4), (b) (6) | 23 Oct 2020 13:45:37 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 28 Sep 2020 22:53:49 |
| Data point term sent to Coder | (b) (4) | |
| Coding entries removed. | System | 28 Sep 2020 21:27:02 |
| | (b) (4), (b) (6) | 28 Sep 2020 21:26:04 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:09:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| 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) | 12 Aug 2020 20:30:14 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Aug 2020 20:30:14 |
| Data point term sent to Coder | System | 12 Aug 2020 20:29:30 |
| User entered 'Aspirin' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:29:28 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:09:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Uche Ehiemua (b) (4) | 27 Oct 2020 15:47:38 |
| User entered 'No (N)' | (b) (4) | |
| | Joanna Gurrola Mahoney | 12 Aug 2020 20:29:28 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:09:59

[Indication](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'CAROTID ATHEROSCLEROSIS' reason for change: Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 02 Nov 2020 20:30:26 |
| User closed query 'Per DM CLR: Please review Indication and please update to provide the medical condition rather than to record a body part. Please update indication and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify. | (b) (4), (b) (6) | 26 Oct 2020 19:15:15 |
| ' (Site from DM). | | |
| Query 'Per DM CLR: Please review Indication and please update to provide the medical condition rather than to record a body part. Please update indication and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify. | (b) (4), (b) (6) | 28 Sep 2020 21:26:29 |
| ' answered with 'updated.' (Site from DM). | | |
| User entered 'CAROTID ATHEROSCLEROSIS.' reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Sep 2020 21:26:22 |
| User entered 'Carotid Atherosclerosis .' reason for change: Data Entry Error | | 28 Sep 2020 21:26:04 |
| User opened query 'Per DM CLR: Please review Indication and please update to provide the medical condition rather than to record a body part. Please update indication and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify. | | 14 Sep 2020 08:01:42 |
| ' (Site from DM). | | |
| User entered 'Heart' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:29:28 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:09:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '81' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:29:28 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:09:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'mg (mg)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:29:28 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:09:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:29:28 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:09:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'once daily (QD)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:29:28 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:09:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:29:28 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:09:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Oral (ORAL)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:29:28 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:09:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:29:28 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:09:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User closed query 'Per CDM: Response noted however, please review and reconcile start date of CAROTID ATHEROSCLEROSIS on corresponding Med Hist eCRF as start date recorded as 'JUN-2020' and start date of meds 'UNK-2009' (difference of @11 years)?' (Site from DM). | (b) (4), (b) (6) | 27 Nov 2020 15:06:06 |
| Query 'Per CDM: Response noted however, please review and reconcile start date of CAROTID ATHEROSCLEROSIS on corresponding Med Hist eCRF as start date recorded as 'JUN-2020' and start date of meds 'UNK-2009' (difference of @11 years)?' answered with 'Med Hist eCRF has been reviewed and reconciled.' (Site from DM). | Joanna Gurrola Mahoney (b) (4) | 02 Nov 2020 20:32:51 |
| User opened query 'Per CDM: Response noted however, please review and reconcile start date of CAROTID ATHEROSCLEROSIS on corresponding Med Hist eCRF as start date recorded as 'JUN-2020' and start date of meds 'UNK-2009' (difference of @11 years)?' (Site from DM). | (b) (4), (b) (6) | 31 Oct 2020 10:39:06 |
| User closed query 'Per DM CLR: Please review if start date is prior the start date of the associated medical condition. Reconcile and update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 31 Oct 2020 10:34:37 |
| Query 'Per DM CLR: Please review if start date is prior the start date of the associated medical condition. Reconcile and update as appropriate.' answered with 'Start date is correct. Patient was placed 81mg aspirin prophylactically before for CAROTID ATHEROSCLEROSIS before having an episode.' (Site from DM). | Uche Ehiemua (b) (4) (b) (4) | 27 Oct 2020 15:48:46 |
| User opened query 'Per DM CLR: Please review if start date is prior the start date of the associated medical condition. Reconcile and update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 17 Oct 2020 06:22:27 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 13 Aug 2020 11:20:26 |

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EAB) (1725)

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US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:09:59

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). User entered 'UN UNK 2009' | System | 12 Aug 2020 20:29:28 |
| | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:29:28 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:29:28 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:09:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:29:28 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:09:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:29:28 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:09:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:29:28 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:09:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Aug 2020 20:29:28 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Aug 2020 20:29:28 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 12 Aug 2020 20:29:28 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:09:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: OTHER UROLOGICALS, PRODUCT: SITOSTEROL, PRODUCTSYNONYM: BETA-SITOSTEROL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 28 Sep 2020 22:35:48 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 28 Sep 2020 22:35:48 |
| Data point term sent to Coder | System | 28 Sep 2020 21:04:01 |
| Coding entries removed. | (b) (4), (b) (6) | 28 Sep 2020 21:03:31 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: OTHER UROLOGICALS, PRODUCT: SITOSTEROL, PRODUCTSYNONYM: BETA SITOSTEROL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Aug 2020 23:05:19 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Aug 2020 23:05:19 |
| Data point term sent to Coder | System | 12 Aug 2020 20:32:34 |
| User entered 'Beta Sitosterol' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:31:38 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:09:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:31:38 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:09:59

[Indication](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User closed query 'Per DM CLR: Please review Indication and please update to provide the medical condition rather than to record a body part. Please update indication and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify. ' (Site from DM). | (b) (4), (b) (6) | 26 Oct 2020 19:16:18 |
| Query 'Per DM CLR: Please review Indication and please update to provide the medical condition rather than to record a body part. Please update indication and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify. ' answered with 'Medical history updated.' (Site from DM). | (b) (4), (b) (6) | 28 Sep 2020 21:03:53 |
| User entered 'Benign prostatic hyperplasia' reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Sep 2020 21:03:31 |
| User opened query 'Per DM CLR: Please review Indication and please update to provide the medical condition rather than to record a body part. Please update indication and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify. ' (Site from DM). | (b) (4), (b) (6) | 14 Sep 2020 08:02:01 |
| User entered 'Prostate' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:31:38 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:09:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '1' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:31:38 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:09:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'tablet (TABLET)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:31:38 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:09:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:31:38 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:09:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'once daily (QD)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:31:38 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:09:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:31:38 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:09:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Oral (ORAL)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:31:38 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:09:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:31:38 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:09:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 13 Aug 2020 11:20:30 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 12 Aug 2020 20:31:38 |
| User entered 'UN UNK 2009' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:31:38 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '0' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:31:38 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:09:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:31:38 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:09:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:31:38 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:09:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:31:38 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:09:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Aug 2020 20:31:38 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Aug 2020 20:31:38 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 12 Aug 2020 20:31:38 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:09:59

Name of Medication

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:43 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User closed query 'Per DM CLR: Medication was added with start date 07Sep2020. Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening GASTRITIS should be recorded, and update con med indication or provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 31 Oct 2020 10:39:51 |
| Query 'Per DM CLR: Medication was added with start date 07Sep2020. Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening GASTRITIS should be recorded, and update con med indication or provide clarification. ' answered with 'Condition is not worsening. Patient was unable to get medication refilled until recently.' (Site from DM). | Uche Ehiemua (b) (4) (b) (4) | 27 Oct 2020 15:53:19 |
| User opened query 'Per DM CLR: Medication was added with start date 07Sep2020. Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening GASTRITIS should be recorded, and update con med indication or provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 02 Oct 2020 19:22:36 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 09 Sep 2020 03:07:33 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 09 Sep 2020 03:07:33 |
| Data point term sent to Coder | System | 09 Sep 2020 03:06:45 |
| User entered 'omeprazole' | Shannon Moyer (b) (4) (b) (4) | 09 Sep 2020 03:05:55 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:09:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:43 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Shannon Moyer (b) (4) | 09 Sep 2020 03:05:55 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:09:59

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:43 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Gastritis' | Shannon Moyer (b) (4) | 09 Sep 2020 03:05:55 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:09:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:43 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '40' | Shannon Moyer (b) (4) | 09 Sep 2020 03:05:55 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:09:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:43 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'mg (mg)' | Shannon Moyer (b) (4) | 09 Sep 2020 03:05:55 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:09:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:43 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 09 Sep 2020 03:05:55 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:09:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:43 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'once daily (QD)' | Shannon Moyer (b) (4) | 09 Sep 2020 03:05:55 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:09:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:43 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 09 Sep 2020 03:05:55 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:09:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:43 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Oral (ORAL)' | Shannon Moyer (b) (4) | 09 Sep 2020 03:05:55 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:09:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:43 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Shannon Moyer (b) (4) | 09 Sep 2020 03:05:55 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:09:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:43 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '7 Sep 2020' | Shannon Moyer (b) (4) | 09 Sep 2020 03:05:55 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:43 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '0' | Shannon Moyer (b) (4) | 09 Sep 2020 03:05:55 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:09:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:43 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' reason for change: Data Entry Error | Uche Ehiemua (b) (4) | 27 Oct 2020 15:53:54 |
| User entered 'Yes (Y)' | Shannon Moyer (b) (4) | 09 Sep 2020 03:05:55 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:09:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:43 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '29 Sep 2020' reason for change: Data Entry Error | Uche Ehiemua (b) (4) | 27 Oct 2020 15:53:54 |
| User entered empty. | (b) (4) | |
| | Shannon Moyer (b) (4) | 09 Sep 2020 03:05:55 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:09:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:43 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Shannon Moyer (b) (4) | 09 Sep 2020 03:05:55 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:09:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:43 |
| User entered '1' | System | 09 Sep 2020 03:05:55 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:43 |
| User entered '1' | System | 09 Sep 2020 03:05:55 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:43 |
| User entered '804 (804)' | System | 09 Sep 2020 03:05:55 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:09:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:54 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 15 Sep 2020 22:08:45 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 15 Sep 2020 22:08:45 |
| Data point term sent to Coder | System | 15 Sep 2020 22:08:08 |
| User entered 'Tylenol' | (b) (4), (b) (6) | 15 Sep 2020 22:07:56 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:09:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:54 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Sep 2020 22:07:56 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:09:59

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:54 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN IN INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN IN INJECTION SITE did not meet the AE reporting criteria.' (Site from DM). | (b) (4), (b) (6) | 31 Oct 2020 10:40:50 |
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN IN INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN IN INJECTION SITE did not meet the AE reporting criteria.' answered with 'As per protocol this is related to dosing. The solicited AR did not meet the AE criteria. ' (Site from DM). | (b) (4), (b) (6) | 07 Oct 2020 21:00:56 |
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. Otherwise provide clarification' canceled (Site from DM). | (b) (4), (b) (6) | 02 Oct 2020 22:18:07 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:09:59

[Indication](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN IN INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN IN INJECTION SITE did not meet the AE reporting criteria.' (Site from DM). | (b) (4), (b) (6) | 02 Oct 2020 22:18:04 |
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. Otherwise provide clarification' (Site from DM). | (b) (4), (b) (6) | 02 Oct 2020 19:26:27 |
| User entered 'Pain in injection site' | (b) (4), (b) (6) | 15 Sep 2020 22:07:56 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:09:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:54 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '500' | (b) (4), (b) (6) | 15 Sep 2020 22:07:56 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:09:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:54 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 15 Sep 2020 22:07:56 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:09:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:54 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | (b) (4), (b) (6) | 15 Sep 2020 22:07:56 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:09:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:54 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'three times daily (TID)' | (b) (4), (b) (6) | 15 Sep 2020 22:07:56 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:09:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:54 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | (b) (4), (b) (6) | 15 Sep 2020 22:07:56 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:09:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:54 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 15 Sep 2020 22:07:56 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:09:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:54 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | (b) (4), (b) (6) | 15 Sep 2020 22:07:56 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:09:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:54 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '9 Sep 2020' | (b) (4), (b) (6) | 15 Sep 2020 22:07:56 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:54 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '0' | (b) (4), (b) (6) | 15 Sep 2020 22:07:56 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:09:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:54 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 15 Sep 2020 22:08:06 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 15 Sep 2020 22:08:06 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 15 Sep 2020 22:08:06 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 15 Sep 2020 22:07:56 |
| User entered empty. | (b) (4), (b) (6) | 15 Sep 2020 22:07:56 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:09:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:54 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '11 Sep 2020' | (b) (4), (b) (6) | 15 Sep 2020 22:07:56 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:09:59

Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:54 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User closed query 'Per DM CLR: Was this medication taken for solicited event?=No. However, there is a record of this event in diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 31 Oct 2020 10:40:29 |
| Query 'Per DM CLR: Was this medication taken for solicited event?=No. However, there is a record of this event in diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification. ' answered with 'Updated.' (Site from DM). | Uche Ehiemua (b) (4) (b) (4) | 27 Oct 2020 15:54:52 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Uche Ehiemua (b) (4) (b) (4) | 27 Oct 2020 15:54:22 |
| User opened query 'Per DM CLR: Was this medication taken for solicited event?=No. However, there is a record of this event in diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 17 Oct 2020 06:23:45 |
| User entered 'No (N)' | (b) (4), (b) (6) | 15 Sep 2020 22:07:56 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:09:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:54 |
| User entered '3' | System | 15 Sep 2020 22:07:56 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:54 |
| User entered '1' | System | 15 Sep 2020 22:07:56 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:21:54 |
| User entered '804 (804)' | System | 15 Sep 2020 22:07:56 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:09:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 08 Oct 2020 06:24:20 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 08 Oct 2020 06:24:20 |
| Data point term sent to Coder | System | 08 Oct 2020 06:23:48 |
| User entered 'Esomeprazole' | Nancy Torrence (b) (4) | 08 Oct 2020 06:23:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:09:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Nancy Torrence (b) (4) | 08 Oct 2020 06:23:20 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:09:59

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Gastritis' | Nancy Torrence (b) (4) | 08 Oct 2020 06:23:20 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:09:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '40' | Nancy Torrence (b) (4) | 08 Oct 2020 06:23:20 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:09:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'mg (mg)' | Nancy Torrence (b) (4) | 08 Oct 2020 06:23:20 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:09:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Nancy Torrence (b) (4) | 08 Oct 2020 06:23:20 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:09:59

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'once daily (QD)' | Nancy Torrence (b) (4) | 08 Oct 2020 06:23:20 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:09:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Nancy Torrence (b) (4) | 08 Oct 2020 06:23:20 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:09:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Oral (ORAL)' | Nancy Torrence (b) (4) | 08 Oct 2020 06:23:20 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:09:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Nancy Torrence (b) (4) | 08 Oct 2020 06:23:20 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:09:59

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '30 Sep 2020' | Nancy Torrence (b) (4) | 08 Oct 2020 06:23:20 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '0' | Nancy Torrence (b) (4) | 08 Oct 2020 06:23:20 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:09:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Nancy Torrence (b) (4) | 08 Oct 2020 06:23:20 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:09:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Nancy Torrence (b) (4) | 08 Oct 2020 06:23:20 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:09:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Nancy Torrence (b) (4) | 08 Oct 2020 06:23:20 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:09:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Oct 2020 06:23:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Oct 2020 06:23:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 08 Oct 2020 06:23:20 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:09:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), PRODUCT: SUCRALFATE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 08 Oct 2020 22:47:26 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 08 Oct 2020 22:47:26 |
| Data point term sent to Coder | System | 08 Oct 2020 06:24:49 |
| User entered 'Sucralfate' | Nancy Torrence (b) (4) | 08 Oct 2020 06:24:32 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:09:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Nancy Torrence (b) (4) | 08 Oct 2020 06:24:32 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:09:59

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Gastritis' | Nancy Torrence (b) (4) | 08 Oct 2020 06:24:32 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:09:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '1' | Nancy Torrence (b) (4) | 08 Oct 2020 06:24:32 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:09:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'g (g)' | Nancy Torrence (b) (4) | 08 Oct 2020 06:24:32 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:09:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Nancy Torrence (b) (4) | 08 Oct 2020 06:24:32 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:09:59

[Frequency](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'four times daily (QID)' | Nancy Torrence (b) (4) | 08 Oct 2020 06:24:32 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:09:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Nancy Torrence (b) (4) | 08 Oct 2020 06:24:32 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:09:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Oral (ORAL)' | Nancy Torrence (b) (4) | 08 Oct 2020 06:24:32 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:09:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Nancy Torrence (b) (4) | 08 Oct 2020 06:24:32 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:09:59

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '30 Sep 2020' | Nancy Torrence (b) (4) | 08 Oct 2020 06:24:32 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '0' | Nancy Torrence (b) (4) | 08 Oct 2020 06:24:32 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:09:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Nancy Torrence (b) (4) | 08 Oct 2020 06:24:32 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:09:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Nancy Torrence (b) (4) | 08 Oct 2020 06:24:32 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:09:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Nancy Torrence (b) (4) | 08 Oct 2020 06:24:32 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:09:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 08 Oct 2020 06:24:32 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Oct 2020 06:24:32 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 08 Oct 2020 06:24:32 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:09:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:22:09 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 08 Oct 2020 06:29:23 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 08 Oct 2020 06:29:23 |
| Data point term sent to Coder | System | 08 Oct 2020 06:28:49 |
| User entered 'Influenza Vaccine' | Nancy Torrence (b) (4) (b) (4) | 08 Oct 2020 06:28:16 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:09:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:22:09 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Yes (Y)' | Nancy Torrence (b) (4) | 08 Oct 2020 06:28:16 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:09:59

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:22:09 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'General Health' | Nancy Torrence (b) (4) | 08 Oct 2020 06:28:16 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:09:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:22:09 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'I' | Nancy Torrence (b) (4) | 08 Oct 2020 06:28:16 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:09:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:22:09 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Other (OTHER)' | Nancy Torrence (b) (4) | 08 Oct 2020 06:28:16 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:09:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:22:09 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'INJECTION' | Nancy Torrence (b) (4) | 08 Oct 2020 06:28:16 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:09:59

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:22:09 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'once (ONCE)' | Nancy Torrence (b) (4) | 08 Oct 2020 06:28:16 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:09:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:22:09 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Nancy Torrence (b) (4) | 08 Oct 2020 06:28:16 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:09:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:22:09 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | Nancy Torrence (b) (4) | 08 Oct 2020 06:28:16 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:09:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:22:09 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered empty. | Nancy Torrence (b) (4) | 08 Oct 2020 06:28:16 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:09:59

Start date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:22:09 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '29 Sep 2020' | Nancy Torrence (b) (4) | 08 Oct 2020 06:28:16 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:22:09 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '0' | Nancy Torrence (b) (4) | 08 Oct 2020 06:28:16 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:09:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:22:09 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Nancy Torrence (b) (4) | 08 Oct 2020 06:28:16 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:09:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:22:09 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered '29 Sep 2020' | Nancy Torrence (b) (4) | 08 Oct 2020 06:28:16 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:09:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:22:09 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User entered 'No (N)' | Nancy Torrence (b) (4) | 08 Oct 2020 06:28:16 |
| | (b) (4) | |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:09:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:22:09 |
| User entered empty. | System | 08 Oct 2020 06:28:16 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:22:09 |
| User entered empty. | System | 08 Oct 2020 06:28:16 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 10:22:09 |
| User entered empty. | System | 08 Oct 2020 06:28:16 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:09:59

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 21:44:18 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 04 Nov 2020 19:27:30 |
| 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 19:27:30 |
| Data point term sent to Coder | System | 04 Nov 2020 18:09:19 |
| User entered 'Amoxicillin/clavulanate' | (b) (4), (b) (6) | 04 Nov 2020 18:08:42 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:09:59

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 21:44:20 |
| User entered 'No (N)' | (b) (4), (b) (6) | 04 Nov 2020 18:08:42 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:09:59

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 21:44:23 |
| User entered 'Appendicitis' | (b) (4), (b) (6) | 04 Nov 2020 18:08:42 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:09:59

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 21:44:26 |
| User entered '500/125' | (b) (4), (b) (6) | 04 Nov 2020 18:08:42 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:09:59

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 21:44:29 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 04 Nov 2020 18:08:42 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:09:59

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 21:44:35 |
| User entered empty. | (b) (4), (b) (6) | 04 Nov 2020 18:08:42 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:09:59

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 21:44:41 |
| User entered 'twice daily (BID)' | (b) (4), (b) (6) | 04 Nov 2020 18:08:42 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:09:59

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 21:44:42 |
| User entered empty. | (b) (4), (b) (6) | 04 Nov 2020 18:08:42 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:09:59

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 21:44:45 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 04 Nov 2020 18:08:42 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:09:59

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 21:44:47 |
| User entered empty. | (b) (4), (b) (6) | 04 Nov 2020 18:08:42 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:09:59

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Feb 2021 16:54:27 |
| User closed query 'Per source, start date 28OCT2020. Please review and reconcile. ' (Site from CRA). | (b) (4), (b) (6) | 09 Feb 2021 16:54:23 |
| Query 'Per source, start date 28OCT2020. Please review and reconcile. ' answered with 'per source start date is 29-oct-20' (Site from CRA). | Shannon Moyer (b) (4) | 08 Feb 2021 05:40:00 |
| User opened query 'Per source, start date 28OCT2020. Please review and reconcile. ' (Site from CRA). | (b) (4), (b) (6) | 08 Jan 2021 05:24:57 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 08 Jan 2021 05:24:42 |
| DataPoint Verified. | | 20 Nov 2020 21:44:49 |
| User entered '29 Oct 2020' | | 04 Nov 2020 18:08:42 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:09:59

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 21:44:51 |
| User entered '0' | (b) (4), (b) (6) | 04 Nov 2020 18:08:42 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:09:59

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Feb 2021 16:54:52 |
| User closed query 'Per source, No. Please review and reconcile. ' (Site from CRA). | | 09 Feb 2021 16:54:51 |
| User closed query 'Per DM CLR: Please review if a stop date should be recorded for this Con Med as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. | | 08 Feb 2021 16:17:52 |
| ' (Site from DM). | | |
| Query 'Per DM CLR: Please review if a stop date should be recorded for this Con Med as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. | Shannon Moyer (b) (4) | 08 Feb 2021 05:46:46 |
| ' answered with 'per source medication is ongoing' (Site from DM). | (b) (4) | |
| Query 'Per source, No. Please review and reconcile. ' answered with 'per source medication is ongoing' (Site from CRA). | Shannon Moyer (b) (4) | 08 Feb 2021 05:41:53 |
| | (b) (4) | |
| User opened query 'Per source, No. Please review and reconcile. ' (Site from CRA). | (b) (4), (b) (6) | 08 Jan 2021 05:25:29 |
| DataPoint Un-verified. | | 08 Jan 2021 05:24:08 |
| User opened query 'Per DM CLR: Please review if a stop date should be recorded for this Con Med as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. | | 23 Dec 2020 18:04:52 |
| ' (Site from DM). | | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 22:58:25 |
| User entered 'Yes (Y)' | | 04 Nov 2020 18:08:42 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:09:59

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Feb 2021 16:55:06 |
| User closed query 'Per source, end date 29OCT2020. Please review and reconcile. ' (Site from CRA). | (b) (4), (b) (6) | 09 Feb 2021 16:55:04 |
| Query 'Per source, end date 29OCT2020. Please review and reconcile. ' answered with 'medication is ongoing' (Site from CRA). | Shannon Moyer (b) (4) | 08 Feb 2021 05:42:44 |
| User opened query 'Per source, end date 29OCT2020. Please review and reconcile. ' (Site from CRA). | (b) (4), (b) (6) | 08 Jan 2021 05:25:16 |
| DataPoint Un-verified. | | 08 Jan 2021 05:25:01 |
| DataPoint Verified. | | 20 Nov 2020 22:58:26 |
| User entered empty. | | 04 Nov 2020 18:08:42 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:09:59

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 21:45:03 |
| User entered 'No (N)' | (b) (4), (b) (6) | 04 Nov 2020 18:08:42 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:09:59

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 04 Nov 2020 18:08:42 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 04 Nov 2020 18:08:42 |

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:09:59

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 04 Nov 2020 18:08:42 |

US3252127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:09:59

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 04:40:41 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| User closed query 'Per source, Endoscopy and Colonoscopy are listed as Concomitant Procedures. Please verify if applicable and reactivate pages in EDC.' (Site from CRA). | (b) (4), (b) (6) | 23 Feb 2021 00:24:19 |
| Query 'Per source, Endoscopy and Colonoscopy are listed as Concomitant Procedures. Please verify if applicable and reactivate pages in EDC.' answered with 'per source endoscopy and colonoscopy are listed under medical history as a subject undergone procedure on august 2018.' (Site from CRA). | (b) (4), (b) (6) | 11 Feb 2021 06:04:18 |
| User opened query 'Per source, Endoscopy and Colonoscopy are listed as Concomitant Procedures. Please verify if applicable and reactivate pages in EDC.' (Site from CRA). | (b) (4), (b) (6) | 09 Feb 2021 16:57:04 |
| User closed query 'Concomitant procedures are noted, please review and reconcile. ' (Site from CRA). | (b) (4), (b) (6) | 27 Dec 2020 21:37:18 |
| DataPoint Verified. | (b) (4), (b) (6) | 27 Dec 2020 21:37:15 |
| Query 'Concomitant procedures are noted, please review and reconcile. ' answered with 'updated.' (Site from CRA). | Joanna Gurrola Mahoney (b) (4) | 21 Nov 2020 16:04:30 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Joanna Gurrola Mahoney (b) (4) | 21 Nov 2020 16:04:24 |
| User opened query 'Concomitant procedures are noted, please review and reconcile. ' (Site from CRA). | (b) (4), (b) (6) | 20 Nov 2020 21:46:10 |
| User entered 'No (N)' reason for change: Data Entry Error | Shannon Moyer (b) (4) | 20 Aug 2020 19:26:01 |
| User entered 'Yes (Y)' | Joanna Gurrola Mahoney (b) (4) | 12 Aug 2020 20:37:51 |

US3252127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:09:59

[Procedure/Surgery date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 22:56:43 |
| User entered '28 Oct 2020' | Shannon Moyer (b) (4) | 09 Nov 2020 16:00:07 |
| | (b) (4) | |

US3252127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:09:59

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|-----------------------------|----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 22:56:44 |
| User entered 'Appendectomy' | Shannon Moyer (b) (4) (b) (4) | 09 Nov 2020 16:00:07 |

US3252127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:09:59

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|-----------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 22:56:46 |
| User entered 'Adverse Event (AE)' | Shannon Moyer (b) (4) | 09 Nov 2020 16:00:07 |
| | (b) (4) | |

US3252127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:09:59

[If indication is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 22:56:47 |
| User entered empty. | Shannon Moyer (b) (4) (b) (4) | 09 Nov 2020 16:00:07 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[SAEID](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'USA-US108-2020-MRNA-1273-P301000013' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

Serious

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'Yes (Y)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'No (N)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'No (N)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'Yes (Y)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'No (N)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'No (N)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'No (N)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'Joel' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'Solis' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

Site Address: Street

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User closed query 'Please update the street address to the correct site street address.' (Site from CRA). | (b) (4), (b) (6) | 19 Mar 2021 17:58:01 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| Query 'Please update the street address to the correct site street address.' answered with 'updated correctly' (Site from CRA). | (b) (4), (b) (6) | 24 Feb 2021 04:00:50 |
| User opened query 'Please update the street address to the correct site street address.' (Site from CRA). | (b) (4), (b) (6) | 09 Feb 2021 16:48:24 |
| DataPoint Verified. | | 09 Feb 2021 16:47:42 |
| DataPoint Un-verified. | | 09 Feb 2021 16:47:40 |
| DataPoint Verified. | | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | | 04 Nov 2020 17:48:19 |
| User entered '5201 N. 10th Street' | | 04 Nov 2020 17:47:49 |
| | System | |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'Mcallen' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'TX' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Mar 2021 17:58:04 |
| User closed query 'Please update site postal code to the correct site postal code.' (Site from CRA). | (b) (4), (b) (6) | 19 Mar 2021 17:58:03 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| Query 'Please update site postal code to the correct site postal code.' answered with 'updated postal code' (Site from CRA). | (b) (4), (b) (6) | 24 Feb 2021 04:01:21 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 04:01:11 |
| DataPoint Un-verified. | | 24 Feb 2021 04:01:11 |
| User entered '78504' reason for change: Data Entry Error | | 24 Feb 2021 04:01:11 |
| User opened query 'Please update site postal code to the correct site postal code.' (Site from CRA). | | 09 Feb 2021 16:48:41 |
| DataPoint Verified. | | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | | 04 Nov 2020 17:48:19 |
| User entered 'carmpa' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Nov 2020 20:27:06 |
| User entered 'US' | System | 04 Nov 2020 17:48:34 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '3' | System | 05 Dec 2020 18:20:24 |
| User entered '2' | System | 23 Nov 2020 20:27:18 |
| User entered '1' | System | 04 Nov 2020 17:48:34 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[SAEID](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'USA-US108-2020-MRNA-1273-P301000013' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

Serious

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'Yes (Y)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'No (N)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'No (N)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'Yes (Y)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'No (N)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'No (N)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'No (N)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'Joel' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'Solis' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

Site Address: Street

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User closed query 'Please update the street address to the correct site street address.' (Site from CRA). | (b) (4), (b) (6) | 19 Mar 2021 17:58:01 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| Query 'Please update the street address to the correct site street address.' answered with 'updated correctly' (Site from CRA). | (b) (4), (b) (6) | 24 Feb 2021 04:00:50 |
| User opened query 'Please update the street address to the correct site street address.' (Site from CRA). | (b) (4), (b) (6) | 09 Feb 2021 16:48:24 |
| DataPoint Verified. | | 09 Feb 2021 16:47:42 |
| DataPoint Un-verified. | | 09 Feb 2021 16:47:40 |
| DataPoint Verified. | | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | | 04 Nov 2020 17:48:19 |
| User entered '5201 N. 10th Street' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'Mcallen' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'TX' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

Site Address: Postal Code

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Mar 2021 17:58:04 |
| User closed query 'Please update site postal code to the correct site postal code.' (Site from CRA). | (b) (4), (b) (6) | 19 Mar 2021 17:58:03 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| Query 'Please update site postal code to the correct site postal code.' answered with 'updated postal code' (Site from CRA). | (b) (4), (b) (6) | 24 Feb 2021 04:01:21 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 04:01:11 |
| DataPoint Un-verified. | | 24 Feb 2021 04:01:11 |
| User entered '78504' reason for change: Data Entry Error | | 24 Feb 2021 04:01:11 |
| User opened query 'Please update site postal code to the correct site postal code.' (Site from CRA). | | 09 Feb 2021 16:48:41 |
| DataPoint Verified. | | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | | 04 Nov 2020 17:48:19 |
| User entered 'carmpa' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Nov 2020 20:27:06 |
| User entered 'US' | System | 04 Nov 2020 17:48:34 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '3' | System | 05 Dec 2020 18:20:24 |
| User entered '2' | System | 23 Nov 2020 20:27:18 |
| User entered '1' | System | 04 Nov 2020 17:48:34 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:09:59

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| User entered '04/Nov/2020 12:48' | System | 04 Nov 2020 17:48:34 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:09:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Nov 2020 20:27:06 |
| User entered 'I' | (b) (4), (b) (6) | 04 Nov 2020 17:48:34 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[SAEID](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'USA-US108-2020-MRNA-1273-P301000013' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

Serious

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'Yes (Y)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'No (N)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'No (N)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'Yes (Y)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'No (N)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'No (N)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'No (N)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'Joel' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'Solis' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

Site Address: Street

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User closed query 'Please update the street address to the correct site street address.' (Site from CRA). | (b) (4), (b) (6) | 19 Mar 2021 17:58:01 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| Query 'Please update the street address to the correct site street address.' answered with 'updated correctly' (Site from CRA). | (b) (4), (b) (6) | 24 Feb 2021 04:00:50 |
| User opened query 'Please update the street address to the correct site street address.' (Site from CRA). | (b) (4), (b) (6) | 09 Feb 2021 16:48:24 |
| DataPoint Verified. | | 09 Feb 2021 16:47:42 |
| DataPoint Un-verified. | | 09 Feb 2021 16:47:40 |
| DataPoint Verified. | | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | | 04 Nov 2020 17:48:19 |
| User entered '5201 N. 10th Street' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'Mcallen' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'TX' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

Site Address: Postal Code

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Mar 2021 17:58:04 |
| User closed query 'Please update site postal code to the correct site postal code.' (Site from CRA). | (b) (4), (b) (6) | 19 Mar 2021 17:58:03 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| Query 'Please update site postal code to the correct site postal code.' answered with 'updated postal code' (Site from CRA). | (b) (4), (b) (6) | 24 Feb 2021 04:01:21 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 04:01:11 |
| DataPoint Un-verified. | | 24 Feb 2021 04:01:11 |
| User entered '78504' reason for change: Data Entry Error | | 24 Feb 2021 04:01:11 |
| User opened query 'Please update site postal code to the correct site postal code.' (Site from CRA). | | 09 Feb 2021 16:48:41 |
| DataPoint Verified. | | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | | 04 Nov 2020 17:48:19 |
| User entered 'carmpa' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Nov 2020 20:27:06 |
| User entered 'US' | System | 04 Nov 2020 17:48:34 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '3' | System | 05 Dec 2020 18:20:24 |
| User entered '2' | System | 23 Nov 2020 20:27:18 |
| User entered '1' | System | 04 Nov 2020 17:48:34 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:09:59

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| User entered '23/Nov/2020 15:27' | System | 23 Nov 2020 20:27:18 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:09:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Dec 2020 18:19:13 |
| User entered 'I' | (b) (4), (b) (6) | 23 Nov 2020 20:27:18 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[SAEID](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'USA-US108-2020-MRNA-1273-P301000013' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

Serious

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'Yes (Y)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'No (N)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'No (N)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'Yes (Y)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'No (N)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'No (N)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'No (N)' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'Joel' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'Solis' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

Site Address: Street

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User closed query 'Please update the street address to the correct site street address.' (Site from CRA). | (b) (4), (b) (6) | 19 Mar 2021 17:58:01 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| Query 'Please update the street address to the correct site street address.' answered with 'updated correctly' (Site from CRA). | (b) (4), (b) (6) | 24 Feb 2021 04:00:50 |
| User opened query 'Please update the street address to the correct site street address.' (Site from CRA). | (b) (4), (b) (6) | 09 Feb 2021 16:48:24 |
| DataPoint Verified. | | 09 Feb 2021 16:47:42 |
| DataPoint Un-verified. | | 09 Feb 2021 16:47:40 |
| DataPoint Verified. | | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | | 04 Nov 2020 17:48:19 |
| User entered '5201 N. 10th Street' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'Mcallen' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 17:48:19 |
| User entered 'TX' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

Site Address: Postal Code

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Mar 2021 17:58:04 |
| User closed query 'Please update site postal code to the correct site postal code.' (Site from CRA). | (b) (4), (b) (6) | 19 Mar 2021 17:58:03 |
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| Query 'Please update site postal code to the correct site postal code.' answered with 'updated postal code' (Site from CRA). | (b) (4), (b) (6) | 24 Feb 2021 04:01:21 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 04:01:11 |
| DataPoint Un-verified. | | 24 Feb 2021 04:01:11 |
| User entered '78504' reason for change: Data Entry Error | | 24 Feb 2021 04:01:11 |
| User opened query 'Please update site postal code to the correct site postal code.' (Site from CRA). | | 09 Feb 2021 16:48:41 |
| DataPoint Verified. | | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | | 04 Nov 2020 17:48:19 |
| User entered 'carmpa' | System | 04 Nov 2020 17:47:49 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Nov 2020 20:27:06 |
| User entered 'US' | System | 04 Nov 2020 17:48:34 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '3' | System | 05 Dec 2020 18:20:24 |
| User entered '2' | System | 23 Nov 2020 20:27:18 |
| User entered '1' | System | 04 Nov 2020 17:48:34 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:09:59

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| User entered '05/Dec/2020 13:20' | System | 05 Dec 2020 18:20:24 |

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:09:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Joel Solis (b) (4) | 05 Mar 2021 20:14:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 05:17:35 |
| User entered 'I' | (b) (4), (b) (6) | 05 Dec 2020 18:20:24 |