

US3762120 (Prod: Wake Forest University Health Sciences)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:41:43

All time stamps listed in this document are displayed in GMT

US3762120

Form: Participant Creation

Data signed: (b) (4) 12 Apr 2021 18:19:59

Generated On: 10 Jun 2021 09:41:43

[Participant ID](#)

US3762120

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

US3762120

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 31 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) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1941 |
| Age | 79 |
| Age Units | YEARS |
| Age (Derived) | 79 |
| Sex | Female <input type="radio"/> Male <input checked="" type="radio"/> |
| Ethnicity | Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/> |
| Race (Check All That Apply) | |
| White | True |
| Black | False |
| Asian | False |
| American Indian or Alaska Native | False |
| Native Hawaiian or other Pacific Islander | False |
| Other | False |
| If race is Other, specify _____ | |
| Unknown | False |
| Not reported | False |

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 31 AUG 2020 |
| Month and Year of Informed Consent (derived) | AUG 2020 |
| Year of Informed Consent (derived) | 2020 |
| Protocol Version | Amendment 1 <input type="radio"/> |
| | Amendment 2 <input type="radio"/> |
| | Amendment 3 <input checked="" type="radio"/> |
| | Amendment 4 <input type="radio"/> |
| | Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| If No, indicate reason for screen fail | Withdrew Consent <input type="radio"/> |
| | Inclusion/Exclusion <input type="radio"/> |
| | Cohort Full <input type="radio"/> |
| | Other <input type="radio"/> |
| If reason for screen fail is Other, specify | |
| Was this participant screened previously? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| If Yes, previous participant number | |
| Enrollment Trigger | 1 |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 22:57:30

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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) 12 Feb 2021 22:57:30

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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) 12 Feb 2021 22:57:30

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| | |
|---|--|
| Condition | TINNITUS |
| Start date (dd MMM yyyy) | 01 JAN 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) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| Condition | GLASSES/CONTACTS |
| Start date (dd MMM yyyy) | 01 JAN 1990 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1990 |
| Start Year (derived) | 1990 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| Condition | CATARACTS |
| Start date (dd MMM yyyy) | UN UNK 2010 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2018 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2010 |
| Start Year (derived) | 2010 |
| Stop Month and Year (derived) | JAN 2018 |
| Stop Year (derived) | 2018 |

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| Condition | HEARING LOSS |
| Start date (dd MMM yyyy) | 01 JAN 2016 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2016 |
| Start Year (derived) | 2016 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| Condition | SKIN CANCER |
| Start date (dd MMM yyyy) | 01 JAN 1980 |
| 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) | 31 DEC 2019 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1980 |
| Start Year (derived) | 1980 |
| Stop Month and Year (derived) | DEC 2019 |
| Stop Year (derived) | 2019 |

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Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 22:57:30

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| | |
|---|--|
| Condition | EXZEMA |
| Start date (dd MMM yyyy) | 01 JAN 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) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| Condition | ACTINIC KERTATOSIS |
| Start date (dd MMM yyyy) | 01 JAN 2000 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2000 |
| Start Year (derived) | 2000 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| Condition | PROXIMAL ATRIAL FIBRILLATION |
| Start date (dd MMM yyyy) | 01 JAN 2019 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | 31 DEC 2019 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2019 |
| Start Year (derived) | 2019 |
| Stop Month and Year (derived) | DEC 2019 |
| Stop Year (derived) | 2019 |

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 12 Feb 2021 22:57:30

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| | |
|---|--|
| Condition | AORTIC ANEURISM |
| Start date (dd MMM yyyy) | 01 JAN 2000 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2000 |
| Start Year (derived) | 2000 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 12 Feb 2021 22:57:30

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| | |
|---|--|
| Condition | HEARTBURN |
| Start date (dd MMM yyyy) | 01 JAN 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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Form: Medical History (11)

Data signed: (b) (4) 12 Feb 2021 22:57:30

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| | |
|---|--|
| Condition | KIDNEY STONES |
| Start date (dd MMM yyyy) | 01 JAN 1967 |
| 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) | 31 DEC 1967 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1967 |
| Start Year (derived) | 1967 |
| Stop Month and Year (derived) | DEC 1967 |
| Stop Year (derived) | 1967 |

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Form: Medical History (13)

Data signed: (b) (4) 12 Feb 2021 22:57:30

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| | |
|---|--|
| Condition | FREQUENT BLOOD/PLASMA DONOR |
| Start date (dd MMM yyyy) | 01 JAN 2016 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2016 |
| Start Year (derived) | 2016 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| Condition | PROSTATE ISSUES (BPH, ENLARGED) |
| Start date (dd MMM yyyy) | 01 JAN 2016 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2016 |
| Start Year (derived) | 2016 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| Condition | SEMINOMA, LEFT TESTICLE |
| Start date (dd MMM yyyy) | 01 JAN 1989 |
| 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) | 31 DEC 1989 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1989 |
| Start Year (derived) | 1989 |
| Stop Month and Year (derived) | DEC 1989 |
| Stop Year (derived) | 1989 |

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| Condition | SOME TYPE OF SKIN CANCER |
| Start date (dd MMM yyyy) | 01 JAN 1980 |
| 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) | 31 DEC 1980 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1980 |
| Start Year (derived) | 1980 |
| Stop Month and Year (derived) | DEC 1980 |
| Stop Year (derived) | 1980 |

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| Condition | PROXIMAL ATRIAL FIBRILLATION |
| 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 (18)

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 31 AUG 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 15:15 (24 HR) |
| Vital Signs Date and Time (derived) | 31 AUG 2020 15:15 |
| Height (<i>xxx.x</i>) | 172.5 cm |
| Weight (<i>xxx.x</i>) | 176 lb |
| BMI (<i>xxx.x</i>) | 26.88511 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) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 22:57:30

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 31 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) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

What was the date of randomization? (dd MMM yyyy) 31 AUG 2020

What was the participant's randomization number? 189264

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) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

| | |
|--------|---------------|
| 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) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

| | |
|-------------------------------------|--|
| 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) | 31 AUG 2020 |
| Time of assessment (00:00-23:59) | 15:15 (24 HR) |
| Vital Signs Date and Time (derived) | 31 AUG 2020 15:15 |
| Temperature (xxx.x) | 98.3 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 48 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 132 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 68 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 31 AUG 2020 |
| Time of assessment (00:00-23:59) | 16:50 (24 HR) |
| Vital Signs Date and Time (derived) | 31 AUG 2020 16:50 |
| Temperature (xxx.x) | 96.8 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 48 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 128 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 67 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 22:57:30

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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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 16:18 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 16:18

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) 12 Feb 2021 22:57:30

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| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 31 AUG 2020 |
| Collection time (00:00-23:59) | 3:58 (24 HR) |
| Collection date and time (derived) | 31 AUG 2020 3:58 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 31 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 16:04 | 31 AUG 2020 16:04 |
| Nasopharyngeal Swab 2 | No | | |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 16:48

PC Open Date & Time

31 AUG 2020 16:38

PC Close Date & Time

31 AUG 2020 19:08

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

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

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

31 AUG 2020 20:03

PC Close Date & Time

01 SEP 2020 11:59

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:43

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

97.7 °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

01 SEP 2020 18:46

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

02 SEP 2020 17:54

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 13:04

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:43

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

97.7 °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

04 SEP 2020 13:17

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

05 SEP 2020 13:14

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 15:05

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

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

31 AUG 2020 16:49

PC Open Date & Time

31 AUG 2020 16:38

PC Close Date & Time

31 AUG 2020 19:08

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

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 ☐

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.**

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

PC Open Date & Time

31 AUG 2020 20:03

PC Close Date & Time

01 SEP 2020 11:59

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:43

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 ☐

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

4

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)**

6

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

01 SEP 2020 18:50

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:43

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 ☐

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

1

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)**

3

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

02 SEP 2020 17:56

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:43

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

4

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

03 SEP 2020 13:05

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:43

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

04 SEP 2020 13:17

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:43

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)**

1

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 - **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

05 SEP 2020 13:15

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:43

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

06 SEP 2020 15:06

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 31 AUG 2020 16:49 |
| PC Open Date & Time | 31 AUG 2020 16:38 |
| PC Close Date & Time | 31 AUG 2020 19:08 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

31 AUG 2020 20:03

PC Close Date & Time

01 SEP 2020 11:59

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

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 ☒

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 01 SEP 2020 18:51 |
| PC Open Date & Time | 01 SEP 2020 12:00 |
| PC Close Date & Time | 02 SEP 2020 11:59 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

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 ☒

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 02 SEP 2020 17:57 |
| PC Open Date & Time | 02 SEP 2020 12:00 |
| PC Close Date & Time | 03 SEP 2020 11:59 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

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 ☒

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 03 SEP 2020 13:06 |
| PC Open Date & Time | 03 SEP 2020 12:00 |
| PC Close Date & Time | 04 SEP 2020 11:59 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

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 ☒

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 04 SEP 2020 13:18 |
| PC Open Date & Time | 04 SEP 2020 12:00 |
| PC Close Date & Time | 05 SEP 2020 11:59 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 05 SEP 2020 13:15 |
| PC Open Date & Time | 05 SEP 2020 12:00 |
| PC Close Date & Time | 06 SEP 2020 11:59 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

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)

68 of 2434

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 06 SEP 2020 15:06 |
| PC Open Date & Time | 06 SEP 2020 12:00 |
| PC Close Date & Time | 07 SEP 2020 11:59 |

US3762120

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:57:29

Generated On: 10 Jun 2021 09:41:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762120

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:57:29

Generated On: 10 Jun 2021 09:41:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762120

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:57:29

Generated On: 10 Jun 2021 09:41:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762120

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:57:29

Generated On: 10 Jun 2021 09:41:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762120

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:57:29

Generated On: 10 Jun 2021 09:41:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762120

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:57:29

Generated On: 10 Jun 2021 09:41:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762120

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

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

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

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

| | |
|-------------------------------------|---|
| 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) | 28 SEP 2020 |
| Time of assessment (00:00-23:59) | 14:02 (24 HR) |
| Vital Signs Date and Time (derived) | 28 SEP 2020 14:02 |
| Temperature (xxx.x) | 97.9 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 61 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 111 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 48 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

| | |
|-------------------------------------|---|
| 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) | 28 SEP 2020 |
| Time of assessment (00:00-23:59) | 15:13 (24 HR) |
| Vital Signs Date and Time (derived) | 28 SEP 2020 15:13 |
| Temperature (xxx.x) | 97.8 F |
| Route of measurement | Oral <input checked="" type="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 52 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 118 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 73 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3762120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

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) 28 SEP 2020

What was the treatment time? (00:00-23:59) 14:43 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 14:43

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

US3762120

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 28 SEP 2020 |
| Collection time (00:00-23:59) | 14:09 (24 HR) |
| Collection date and time (derived) | 28 SEP 2020 14:09 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 28 SEP 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 14:11 | 28 SEP 2020 14:11 |
| Nasopharyngeal Swab 2 | No | | |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 15:15

PC Open Date & Time

28 SEP 2020 15:03

PC Close Date & Time

28 SEP 2020 17:33

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °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 | 28 SEP 2020 20:33 |
| PC Open Date & Time | 28 SEP 2020 18:28 |
| PC Close Date & Time | 29 SEP 2020 11:59 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:43

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

99.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 19:35

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:43

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

100.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 18:00

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

01 OCT 2020 17:05

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:43

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

97.7 °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

02 OCT 2020 16:45

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 07:49

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:43

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 16:00

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

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

28 SEP 2020 15:16

PC Open Date & Time

28 SEP 2020 15:03

PC Close Date & Time

28 SEP 2020 17:33

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

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

28 SEP 2020 20:34

PC Open Date & Time

28 SEP 2020 18:28

PC Close Date & Time

29 SEP 2020 11:59

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

70

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

29 SEP 2020 19:37

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:43

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 ☐

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

83

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)**

83

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

30 SEP 2020 18:01

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:43

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 ☐

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

70

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)**

80

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

01 OCT 2020 17:06

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:43

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

50

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

02 OCT 2020 16:46

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:43

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

20

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

04 OCT 2020 07:49

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:43

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

30

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

04 OCT 2020 16:01

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 28 SEP 2020 15:16 |
| PC Open Date & Time | 28 SEP 2020 15:03 |
| PC Close Date & Time | 28 SEP 2020 17:33 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 28 SEP 2020 20:35 |
| PC Open Date & Time | 28 SEP 2020 18:28 |
| PC Close Date & Time | 29 SEP 2020 11:59 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

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 ☒

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 29 SEP 2020 19:38 |
| PC Open Date & Time | 29 SEP 2020 12:00 |
| PC Close Date & Time | 30 SEP 2020 11:59 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

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 ☒

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 30 SEP 2020 18:02 |
| PC Open Date & Time | 30 SEP 2020 12:00 |
| PC Close Date & Time | 01 OCT 2020 11:59 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

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 ☒

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 01 OCT 2020 17:06 |
| PC Open Date & Time | 01 OCT 2020 12:00 |
| PC Close Date & Time | 02 OCT 2020 11:59 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

110 of 2434

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 02 OCT 2020 16:47 |
| PC Open Date & Time | 02 OCT 2020 12:00 |
| PC Close Date & Time | 03 OCT 2020 11:59 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

112 of 2434

EAB) (1725)

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 04 OCT 2020 07:50 |
| PC Open Date & Time | 03 OCT 2020 12:00 |
| PC Close Date & Time | 04 OCT 2020 11:59 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

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 ☒

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 04 OCT 2020 16:02 |
| PC Open Date & Time | 04 OCT 2020 12:00 |
| PC Close Date & Time | 05 OCT 2020 11:59 |

US3762120

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 10 Jun 2021 09:41:43

| | |
|--|--|
| TIMEPOINT | DAY 8 |
| Is there any SWELLING/HARDNESS AT INJECTION SITE? | Yes <input type="checkbox"/> |
| | No <input checked="" type="checkbox"/> |
| PC Time stamp | 05 OCT 2020 13:48 |
| PC Open Date & Time | 05 OCT 2020 12:00 |
| PC Close Date & Time | 06 OCT 2020 11:59 |

US3762120

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| TIMEPOINT | DAY 8 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 05 OCT 2020 13:48 |
| PC Open Date & Time | 05 OCT 2020 12:00 |
| PC Close Date & Time | 06 OCT 2020 11:59 |

US3762120

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:57:29

Generated On: 10 Jun 2021 09:41:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762120

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:57:29

Generated On: 10 Jun 2021 09:41:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762120

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:57:29

Generated On: 10 Jun 2021 09:41:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762120

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:57:29

Generated On: 10 Jun 2021 09:41:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762120

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:57:29

Generated On: 10 Jun 2021 09:41:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762120

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:57:29

Generated On: 10 Jun 2021 09:41:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762120

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 04 NOV 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 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 04 NOV 2020 |
| Time of assessment (00:00-23:59) | 09:21 (24 HR) |
| Vital Signs Date and Time (derived) | 04 NOV 2020 09:21 |
| Temperature (xxx.x) | 97.7 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 58 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 112 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 72 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

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.

US3762120

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 NOV 2020

Collection time (00:00-23:59)

09:40 (24 HR)

Collection date and time (derived)

04 NOV 2020 09:40

US3762120

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:57:30

Generated On: 10 Jun 2021 09:41:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| 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 | 04 NOV 2020 12:14:51 |
| Patient Cloud Open Date & Time | 31 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 04 NOV 2020 23:59 |

US3762120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

11 NOV 2020 07:15:47

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3762120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| TIMEPOINT | DAY 78 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 14 NOV 2020 08:43:44 |
| Patient Cloud Open Date & Time | 14 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 18 NOV 2020 23:59 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| TIMEPOINT | DAY 82 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 NOV 2020 07:46:47

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| TIMEPOINT | DAY 96 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 02 DEC 2020 08:00:28 |
| Patient Cloud Open Date & Time | 02 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 06 DEC 2020 23:59 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

09 DEC 2020 11:11:58

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

16 DEC 2020 10:55:54

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

23 DEC 2020 08:31:10

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

31 DEC 2020 10:07:20

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

07 JAN 2021 09:10:19

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

15 JAN 2021 11:54:44

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 07:29:18

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

27 JAN 2021 08:11:35

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

04 FEB 2021 12:30:13

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

10 FEB 2021 07:53:47

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

18 FEB 2021 12:42:47

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| TIMEPOINT | DAY 180 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission | 24 FEB 2021 13:45:20 |
| Patient Cloud Open Date & Time | 24 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 28 FEB 2021 23:59 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

03 MAR 2021 06:22:23

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

10 MAR 2021 07:09:24

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| TIMEPOINT | DAY 201 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission | 17 MAR 2021 09:39:49 |
| Patient Cloud Open Date & Time | 17 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 21 MAR 2021 23:59 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

24 MAR 2021 09:34:55

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| TIMEPOINT | DAY 215 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 | 31 MAR 2021 19:02:27 |
| Patient Cloud Open Date & Time | 31 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 04 APR 2021 23:59 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

07 APR 2021 07:00:07

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

14 APR 2021 07:20:42

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

23 APR 2021 12:01:00

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

01 MAY 2021 07:15:44

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

DAY 250

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

DAY 257

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| TIMEPOINT | DAY 264 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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°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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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°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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 2021 00:01 |
| Patient Cloud Close Date & Time | 18 JUL 2021 23:59 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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°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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| 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"/> |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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°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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| 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"/> |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| 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"/> |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 17 OCT 2021 23:59 |
|---|-------------------|

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

DAY 425

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 27 OCT 2021 00:01 |
|--|-------------------|

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 31 OCT 2021 23:59 |
|---|-------------------|

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| 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"/> |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 05 DEC 2021 23:59 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 12 DEC 2021 23:59 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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°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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| TIMEPOINT | DAY 481 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| TIMEPOINT | DAY 488 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| 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 <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"/> |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| TIMEPOINT | DAY 516 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

DAY 530

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| 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"/> |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| 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"/> |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| TIMEPOINT | DAY 628 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

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05 JUN 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

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

Date and time of submission

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08 JUN 2022 00:01

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12 JUN 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

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19 JUN 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

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26 JUN 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| 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"/> |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

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03 JUL 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

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10 JUL 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| TIMEPOINT | DAY 684 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

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17 JUL 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

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24 JUL 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your 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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27 JUL 2022 00:01

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31 JUL 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

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07 AUG 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your 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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10 AUG 2022 00:01

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14 AUG 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:41:43

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

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21 AUG 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

DAY 768

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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 ☐

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 30 OCT 2022 23:59 |
|---|-------------------|

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3762120

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:41:43

| 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 | | 29 MAR 2021 13:35:12 |

US3762120

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 18:30:06

Generated On: 10 Jun 2021 09:41:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762120

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 18:30:06

Generated On: 10 Jun 2021 09:41:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762120

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 18:20:03

Generated On: 10 Jun 2021 09:41:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762120

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 18:20:03

Generated On: 10 Jun 2021 09:41:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762120

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 18:20:03

Generated On: 10 Jun 2021 09:41:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762120

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 18:20:03

Generated On: 10 Jun 2021 09:41:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762120

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 18:20:03

Generated On: 10 Jun 2021 09:41:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762120

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 18:20:03

Generated On: 10 Jun 2021 09:41:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762120

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 18:20:03

Generated On: 10 Jun 2021 09:41:43

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 29 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 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 18:20:03

Generated On: 10 Jun 2021 09:41:43

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) _____

US3762120

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 18:20:03

Generated On: 10 Jun 2021 09:41:43

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.

US3762120

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 18:20:03

Generated On: 10 Jun 2021 09:41:43

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 29 MAR 2021 |
| Collection time (00:00-23:59) | 13:41 (24 HR) |
| Collection date and time (derived) | 29 MAR 2021 13:41 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 18:20:03

Generated On: 10 Jun 2021 09:41:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762120

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

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

US3762120

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3762120

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:41:43

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

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Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:41:43

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3762120

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

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 18:20:02

Generated On: 10 Jun 2021 09:41:43

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 30 DEC 2020 |
|--------------------------|-------------|

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

US3762120

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 18:20:01

Generated On: 10 Jun 2021 09:41:43

Date of updated informed consent (*dd MMM yyyy*) 30 DEC 2020

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*) 30 DEC 2020

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 _____

US3762120

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 18:20:01

Generated On: 10 Jun 2021 09:41:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 DEC 2020

Collection time (00:00-23:59)

14:58 (24 HR)

Collection date and time (derived)

30 DEC 2020 14:58

US3762120

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Apr 2021 18:20:01

Generated On: 10 Jun 2021 09:41:43

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 30 DEC 2020 |
| Collection time (00:00 - 23:59) | 15:00 |
| Collection Date and Time (derived) | 30 DEC 2020 15:00 |

US3762120

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Mar 2021 17:28:29

Generated On: 10 Jun 2021 09:41:43

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Apr 2021 18:19:59

Generated On: 10 Jun 2021 09:41:43

| | |
|--|--|
| AEID | USA-US130-2021-MRNA-1273-P30 1000005 |
| Adverse event | NEPHROLITHIASIS |
| 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) | 21 FEB 2021 |
| 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) | 16 MAR 2021 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 21 FEB 2021 |
| Hospital Discharge Date (dd MMM yyyy) | 25 FEB 2021 |
| 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 (1)

Data signed: (b) (4) 12 Apr 2021 18:19:59

Generated On: 10 Jun 2021 09:41:43

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

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Apr 2021 18:19:59

Generated On: 10 Jun 2021 09:41:43

PATIENT WENT TO
EMERGENCY ROOM ON 21 FEB
2021 FOR FATIGUE, CHILLS,
ACHES, ABDOMINAL PAIN,
NAUSEA, AND VOMITING. LAB
STUDIES CAME BACK
NEGATIVE FOR COVID-19 AND
OVERALL WITHOUT FOCAL
ABNORMALITY. EKG NORMAL,
CT OF PELVIS SHOWS 8MM
PROXIMAL RIGHT URETERAL
STONE, URINALYSIS SHOWS
SIGNIFICANT NITRITES,
BLOOD, AND LEUKOCYTES. IV
ROCEPHIN ADMINISTERED,
BLOOD CULTURES DRAWN.
CYSTOSCOPY WITH STENT
PLACEMENT IN RIGHT URETER
OCCURRED ON 22 FEB 2021.

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

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Apr 2021 18:19:59

Generated On: 10 Jun 2021 09:41:43

| | |
|--|--|
| AEID | USA-US130-2021-MRNA-1273-P30 1000005 |
| Adverse event | METHICILLIN-SUSCEPTIBLE STAPHYLOCOCCUS AUREUS BACTEREMIA |
| 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) | 13 MAR 2021 |
| 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) | 17 MAR 2021 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 14 MAR 2021 |
| Hospital Discharge Date (dd MMM yyyy) | 17 MAR 2021 |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> |
| PRODUCTION RELEASE (v12.003 EAB) (1725) | 341 of 2434 |

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Apr 2021 18:19:59

Generated On: 10 Jun 2021 09:41:43

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Apr 2021 18:19:59

Generated On: 10 Jun 2021 09:41:43

PATIENT IS A 79-YEAR-OLD MALE WHO PRESENTED WITH FEVER AT HOME. PATIENT REPORTED THAT HIS TEMPERATURE WAS NORMAL THAT MORNING, BUT THAT EVENING HE FELT WARM AND WITH CHILLS. HE CHECKED HIS TEMPERATURE ORALLY AND IT WAS MEASURED AT ABOUT 102 AT HOME. PATIENT ALSO REPORTED THAT HE HAD RIGHT FLANK PAIN AND TROUBLE INITIATING URINATION BECAUSE OF THE STENT, HOWEVER, THIS IS NOT NEW AND HAS BEEN EXPERIENCING THIS FOR A WHILE. IT WAS DISCOVERED PATIENT HAD A REOCCURRING INCIDENT OF METHICILLIN-SUSCEPTIBLE STAPHYLOCOCCUS AUREUS. ADMITTED ON 3/14 FOR FEVER AND CHILLS, FOUND TO HAVE E. COLI UTI IN SETTING OF RECENT URETERAL STENT PLACEMENT. HE RECEIVED IV ANTIBIOTICS AND WAS FOLLOWED CLOSELY BY ID AND UROLOGY. HAD A STENT REMOVAL, STONES BLASTED, NEW STENT PLACE. COVID-19 TEST WAS PERFORMED ON 3/14/2021 AND RESULTED AS

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Apr 2021 18:19:59

Generated On: 10 Jun 2021 09:41:43

NEGATIVE FOR COVID-19.
SIGNIFICANT DIAGNOSTIC
LABS INCLUDE CBC; 3/14/2021
WBC 11.0, HGB 10.8, HCT 31.0,
3/15/2021 WBC 7.8, HGB 10.4,
HCT 30.6, 3/16/2021 WBC 3.5,
HGT 10.9, HCT 31.7, 3/17/2021
WBC 7.6, HGB 11.2, HCT 32.3.
DISCHARGED ON 3/17/2021
AWAITING AN UPDATE AFTER
VISIT WITH PCP AFTER APRIL
2021

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Apr 2021 18:19:59

Generated On: 10 Jun 2021 09:41:43

| | |
|--|--|
| AEID | USA-US130-2021-MRNA-1273-P30 1000005 |
| Adverse event | E. COLI UTI |
| Was this a medically-attended AE? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Start date (dd MMM yyyy) | 14 MAR 2021 |
| 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 MAR 2021 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 14 MAR 2021 |
| Hospital Discharge Date (dd MMM yyyy) | 17 MAR 2021 |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Apr 2021 18:19:59

Generated On: 10 Jun 2021 09:41:43

| | |
|--|---|
| 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 | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Apr 2021 18:19:59

Generated On: 10 Jun 2021 09:41:43

PATIENT IS A 79-YEAR-OLD MALE WHO PRESENTED WITH FEVER AT HOME. PATIENT REPORTED THAT HIS TEMPERATURE WAS NORMAL THAT MORNING, BUT THAT EVENING HE FELT WARM AND WITH CHILLS. HE CHECKED HIS TEMPERATURE ORALLY AND IT WAS MEASURED AT ABOUT 102 AT HOME. PATIENT ALSO REPORTED THAT HE HAD RIGHT FLANK PAIN AND TROUBLE INITIATING URINATION BECAUSE OF THE STENT, HOWEVER, THIS IS NOT NEW AND HAS BEEN EXPERIENCING THIS FOR A WHILE. IT WAS DISCOVERED PATIENT HAD A REOCCURRING INCIDENT OF METHICILLIN-SUSCEPTIBLE STAPHYLOCOCCUS AUREUS. PATIENT WAS FOUND TO HAVE E. COLI UTI IN SETTING OF RECENT URETERAL STENT PLACEMENT. ADMITTED ON 3/14 FOR FEVER AND CHILLS, FOUND TO HAVE E. COLI UTI IN SETTING OF RECENT URETERAL STENT PLACEMENT. HE RECEIVED IV ANTIBIOTICS AND WAS FOLLOWED CLOSELY BY ID AND UROLOGY. HAD A STENT

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Apr 2021 18:19:59

Generated On: 10 Jun 2021 09:41:43

REMOVAL, STONES BLASTED,
NEW STENT PLACE.
SIGNIFICANT DIAGNOSTIC
LABS INCLUDE CBC; 3/14/2021
WBC 11.0, HGB 10.8, HCT 31.0,
3/15/2021 WBC 7.8, HGB 10.4,
HCT 30.6, 3/16/2021 WBC 3.5,
HGT 10.9, HCT 31.7, 3/17/2021
WBC 7.6, HGB 11.2, HCT 32.3.
DISCHARGED ON 3/17/2021
AWAITING AN UPDATE AFTER
VISIT WITH PCP AFTER APRIL
2021

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Apr 2021 18:19:59

Generated On: 10 Jun 2021 09:41:43

| | |
|--|--|
| AEID | USA-US130-2021-MRNA-1273-P30 1000005 |
| Adverse event | METHICILLIN-SUSCEPTIBLE STAPHYLOCOCCUS AUREUS BACTEREMIA |
| 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) | 21 FEB 2021 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 25 FEB 2021 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 21 FEB 2021 |
| Hospital Discharge Date (dd MMM yyyy) | 25 FEB 2021 |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> |
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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Apr 2021 18:19:59

Generated On: 10 Jun 2021 09:41:43

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

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Apr 2021 18:19:59

Generated On: 10 Jun 2021 09:41:43

79 Y.O. MALE W/ HX AFIB (ON ELIQUIS) AND NEPHROLITHIASIS WITH 8MM PROXIMAL R URETERAL STONE WITH HYDROURETERONEPHROSIS AND STRANDING. FEBRILE TO 102.5 AT OSH, NO LEUKOCYTOSIS, TACHYCARDIC, HYPOTENSIVE. HE WAS TAKEN TO THE OR E2 FOR A RIGHT URETERAL STENT PLACEMENT. ID WAS CONSULTED POSTOPERATIVELY FOR BACTEREMIA DUE TO MSSA.

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

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Apr 2021 18:19:59

Generated On: 10 Jun 2021 09:41:43

AEID USA-US130-2021-MRNA-1273-P30
1000005

Adverse event COMPLICATED URINARY
TRACT INFECTION

Was this a medically-attended AE? Yes ☒
No ☐

Was this a Solicited Adverse Reaction? Yes ☐
No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ☐
No ☒

Start date (dd MMM yyyy) 21 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 25 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes ☒
No ☐

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 21 FEB 2021

Hospital Discharge Date (dd MMM yyyy) 25 FEB 2021

Admitted to ICU? Yes ☐
No ☐
Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Apr 2021 18:19:59

Generated On: 10 Jun 2021 09:41:43

| | |
|--|---|
| 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 | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Apr 2021 18:19:59

Generated On: 10 Jun 2021 09:41:43

PATIENT WENT TO
EMERGENCY ROOM ON 21 FEB
2021 FOR FATIGUE, CHILLS,
ACHES, ABDOMINAL PAIN,
NAUSEA, AND VOMITING. LAB
STUDIES CAME BACK
NEGATIVE FOR COVID-19 AND
OVERALL WITHOUT FOCAL
ABNORMALITY. EKG NORMAL,
CT OF PELVIS SHOWS 8MM
PROXIMAL RIGHT URETERAL
STONE, URINALYSIS SHOWS
SIGNIFICANT NITRITES,
BLOOD, AND LEUKOCYTES. IV
ROCEPHIN ADMINISTERED,
BLOOD CULTURES DRAWN.
CYSTOSCOPY WITH STENT
PLACEMENT IN RIGHT URETER
OCCURRED ON 22 FEB 2021.

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

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 18:20:01

Generated On: 10 Jun 2021 09:41:43

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

Yes ☒

No ☐

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

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

Name of Medication METAPROLOL

Prophylaxis Yes ☒
No ☐

Indication THORACIC ANEURISM
PROPHYLAXIS

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

| | | |
|--|--------------------------|----------------------------------|
| | Intraocular | <input type="radio"/> |
| | 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) | | 01 JAN 2000 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | | 1 |
| Interval Dosage Unit Number (derived) | | 1 |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

Name of Medication LOSARTAN

Prophylaxis Yes ☒
No ☐

Indication THORACIC ANEURISM
PROPHYLAXIS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

| | | |
|--|--------------------------|----------------------------------|
| | Intraocular | <input type="radio"/> |
| | 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) | | 01 JAN 2000 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | | 1 |
| Interval Dosage Unit Number (derived) | | 1 |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

Name of Medication ATORVASTATIN

Prophylaxis Yes ☒
No ☐

Indication CHOLESTEROL MANAGEMENT

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 (3)

Data signed: (b) (4) 12 Apr 2021 18:20:00

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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) | | 01 JAN 1995 |
| 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) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

Name of Medication APIXIBAN

Prophylaxis Yes ☒
No ☐

Indication PAROXYSMAL ATRIAL
FIBRILLATION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

| | | |
|--|--------------------------|----------------------------------|
| | Intraocular | <input type="radio"/> |
| | 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) | | 01 JAN 2019 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | | 2 |
| Interval Dosage Unit Number (derived) | | 1 |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

Name of Medication TERAZOSIN

Prophylaxis Yes ☒
No ☐

Indication BPH

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 (5)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

| | | |
|--|--------------------------|----------------------------------|
| | 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) | 01 JAN 2016 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

Name of Medication TADALAFIL

Prophylaxis Yes ☒
No ☐

Indication BPH

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)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

| | | |
|--|--------------------------|----------------------------------|
| | 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) | 01 JAN 2016 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication PREVENTION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

| | | |
|--|--------------------------|----------------------------------|
| | 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) | 01 JAN 2016 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

Name of Medication VITAMIN B12

Prophylaxis Yes ☒
No ☐

Indication PREVENTION

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

| | | |
|--|--------------------------|----------------------------------|
| | 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) | 01 JAN 2016 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

Name of Medication ROCEPHIN

Prophylaxis Yes ☐
No ☒

Indication NEPHROLITHIASIS

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 ☐

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

| | | |
|--|---|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input checked="" type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 21 FEB 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes <input type="checkbox"/> | |
| | No <input checked="" type="checkbox"/> | |
| If not Ongoing, End date (dd MMM yyyy) | 21 FEB 2021 | |
| 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 (10)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication NEPHROLITHIASIS

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | | 21 FEB 2021 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 22 FEB 2021 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

Name of Medication DAPTOMYCIN

Prophylaxis Yes ☐
No ☒

Indication MSSA BACTEREMIA

Dose per administration 625

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 Q24

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) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input checked="" type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 25 FEB 2021 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 28 FEB 2021 |
| 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 (12)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

Name of Medication BACTRIM DS

Prophylaxis Yes ☐
No ☒

Indication E. COLI UTI

Dose per administration 800-160

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 (12)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

| | | |
|--|--------------------------|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 25 FEB 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 27 MAR 2021 | | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 2 | |
| 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 (13)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication BPH

Dose per administration 0.4

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

| | | |
|--|--------------------------|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 25 FEB 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 7 MAR 2021 |
| 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 (14)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

Name of Medication LINEZOLID

Prophylaxis Yes ☐
No ☒

Indication MSSA BACTEREMIA

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | | 1 MAR 2021 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 7 MAR 2021 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | | 2 |
| 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 (15)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

Name of Medication CEFTIN

Prophylaxis Yes ☐
No ☒

Indication E. COLI UTI

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

| | | |
|--|--------------------------|----------------------------------|
| | 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) | 18 MAR 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | 29 MAR 2021 | |
| 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 (16)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

Name of Medication MAXIPIME

Prophylaxis Yes ☐
No ☒

Indication E. COLI UTI

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input checked="" type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 14 MAR 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | 14 MAR 2021 | |
| 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 (17)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

Name of Medication FLU VACCINE

Prophylaxis Yes ☐
No ☒

Indication PROPHYLAXIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 12 Apr 2021 18:20:00

Generated On: 10 Jun 2021 09:41:43

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

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 18:20:01

Generated On: 10 Jun 2021 09:41:43

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Apr 2021 18:20:01

Generated On: 10 Jun 2021 09:41:43

| Procedure/Surgery date (dd MMM yyyy) | Procedure/Surgery | Indication | If indication is Other, specify |
|---|--|---------------|---------------------------------|
| 22 FEB 2021 | CYSTOSCOPY WITH STENT IN RIGHT URETER | Adverse Event | |

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:41:43

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:41:43

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 ☐

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Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 12 Apr 2021 18:20:02

Generated On: 10 Jun 2021 09:41:43

| | |
|--|--|
| SAEID | USA-US130-2021-MRNA-1273-P301000005 |
| 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 | JOHN |
| Investigator's Last Name | SANDERS |
| Site Address: Street | 100 MEDICAL CENTER BLVD |
| Site Address: City | WINSTON-SALEM |
| Site Address: State | NC |
| Site Address: Postal Code | 27157 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 8 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Apr 2021 18:20:02

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| SAEID | USA-US130-2021-MRNA-1273-P301000005 |
| 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 | JOHN |
| Investigator's Last Name | SANDERS |
| Site Address: Street | 100 MEDICAL CENTER BLVD |
| Site Address: City | WINSTON-SALEM |
| Site Address: State | NC |
| Site Address: Postal Code | 27157 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 8 |
| Date of submission (Pre-filled from custom function) | 22/FEB/2021 13:21 |
| 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 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Apr 2021 18:20:02

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| SAEID | USA-US130-2021-MRNA-1273-P301000005 |
| 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 | JOHN |
| Investigator's Last Name | SANDERS |
| Site Address: Street | 100 MEDICAL CENTER BLVD |
| Site Address: City | WINSTON-SALEM |
| Site Address: State | NC |
| Site Address: Postal Code | 27157 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 8 |
| Date of submission (Pre-filled from custom function) | 18/MAR/2021 10:10 |
| 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 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Apr 2021 18:20:02

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| SAEID | USA-US130-2021-MRNA-1273-P301000005 |
| 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 | JOHN |
| Investigator's Last Name | SANDERS |
| Site Address: Street | 100 MEDICAL CENTER BLVD |
| Site Address: City | WINSTON-SALEM |
| Site Address: State | NC |
| Site Address: Postal Code | 27157 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 8 |
| Date of submission (Pre-filled from custom function) | 24/MAR/2021 16:52 |
| 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 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Apr 2021 18:20:02

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| SAEID | USA-US130-2021-MRNA-1273-P301000005 |
| 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 | JOHN |
| Investigator's Last Name | SANDERS |
| Site Address: Street | 100 MEDICAL CENTER BLVD |
| Site Address: City | WINSTON-SALEM |
| Site Address: State | NC |
| Site Address: Postal Code | 27157 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 8 |
| Date of submission (Pre-filled from custom function) | 24/MAR/2021 22:43 |
| 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 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 12 Apr 2021 18:20:02

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| SAEID | USA-US130-2021-MRNA-1273-P301000005 |
| 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 | JOHN |
| Investigator's Last Name | SANDERS |
| Site Address: Street | 100 MEDICAL CENTER BLVD |
| Site Address: City | WINSTON-SALEM |
| Site Address: State | NC |
| Site Address: Postal Code | 27157 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 8 |
| Date of submission (Pre-filled from custom function) | 26/MAR/2021 06:16 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Data signed: (b) (4) 12 Apr 2021 18:20:02

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| SAEID | USA-US130-2021-MRNA-1273-P301000005 |
| 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 | JOHN |
| Investigator's Last Name | SANDERS |
| Site Address: Street | 100 MEDICAL CENTER BLVD |
| Site Address: City | WINSTON-SALEM |
| Site Address: State | NC |
| Site Address: Postal Code | 27157 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 8 |
| Date of submission (Pre-filled from custom function) | 30/MAR/2021 07:52 |
| 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 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form (7)

Data signed: (b) (4) 12 Apr 2021 18:20:02

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| SAEID | USA-US130-2021-MRNA-1273-P301000005 |
| 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 | JOHN |
| Investigator's Last Name | SANDERS |
| Site Address: Street | 100 MEDICAL CENTER BLVD |
| Site Address: City | WINSTON-SALEM |
| Site Address: State | NC |
| Site Address: Postal Code | 27157 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 8 |
| Date of submission (Pre-filled from custom function) | 08/APR/2021 16:10 |
| 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 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form (8)

Data signed: (b) (4) 12 Apr 2021 18:20:02

Generated On: 10 Jun 2021 09:41:43

| | |
|---|--|
| SAEID | USA-US130-2021-MRNA-1273-P301000005 |
| 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 | JOHN |
| Investigator's Last Name | SANDERS |
| Site Address: Street | 100 MEDICAL CENTER BLVD |
| Site Address: City | WINSTON-SALEM |
| Site Address: State | NC |
| Site Address: Postal Code | 27157 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 8 |
| Date of submission (Pre-filled from custom function) | 09/APR/2021 08:18 |
| 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

US3762120 (Prod: Wake Forest University Health Sciences)

US3762120

Form: Participant Creation

Generated On: 10 Jun 2021 09:41:43

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'US3762120' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 31 Aug 2020 19:34:20 |

US3762120

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:41:43

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | (b) (4) Samantha Wheeler (b) (4) (b) (4) | 31 Aug 2020 20:19:47 |

US3762120

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '31 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 31 Aug 2020 19:34:21 |

US3762120

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Clinic (Clinic)' | (b) (4) Samantha Wheeler (b) (4) (b) (4) | 31 Aug 2020 20:19:47 |

US3762120

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:41:43

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'SCRN' | System | 31 Aug 2020 20:19:47 |

US3762120

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:43

[Date of Birth \(MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered (b) (6) 1941' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 31 Aug 2020 19:34:22 |

US3762120

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:43

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '79' | (b) (4) James Lovette (b) (4) | 03 Sep 2020 18:08:23 |

US3762120

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:43

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'YEARS' | System | 03 Sep 2020 18:08:23 |

US3762120

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:43

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '79' | System | 31 Aug 2020 20:20:15 |

US3762120

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:43

Sex

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User closed query 'Per GCL Lab Recon: GCL recorded the sex as female; However, EDC records sex as male. Please reconcile. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 26 Nov 2020 09:30:44 |
| Query 'Per GCL Lab Recon: GCL recorded the sex as female; However, EDC records sex as male. Please reconcile. ' answered with 'this is a male subject' (Site from DM). | Samantha Wheeler (b) (4) (b) (4) | 24 Oct 2020 22:31:08 |
| User opened query 'Per GCL Lab Recon: GCL recorded the sex as female; However, EDC records sex as male. Please reconcile. ' (Site from DM). | (b) (4), (b) (6) | 23 Oct 2020 01:52:02 |
| User entered 'Male (M)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:08:23 |

US3762120

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:43

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4) James Lovette (b) (4) | 03 Sep 2020 18:08:23 |

US3762120

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:43

[White](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'I' | James Lovette (b) (4) | 03 Sep 2020 18:08:23 |

US3762120

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:43

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:08:23 |

US3762120

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:43

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:08:23 |

US3762120

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:43

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:08:23 |

US3762120

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:43

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:08:23 |

US3762120

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:43

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:08:23 |

US3762120

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:43

[If race is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | (b) (4) James Lovette (b) (4) | 03 Sep 2020 18:08:23 |

US3762120

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:43

[Unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:08:23 |

US3762120

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:43

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:08:23 |

US3762120

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:43

[Date of Informed Consent \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '31 Aug 2020' | (b) (4) Samantha Wheeler (b) (4) (b) (4) | 31 Aug 2020 20:20:15 |

US3762120

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'Aug 2020' | System | 31 Aug 2020 20:20:15 |

US3762120

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '2020' | System | 31 Aug 2020 20:20:15 |

US3762120

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:43

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Amendment 3 (3)' | (b) (4) Samantha Wheeler (b) (4) (b) (4) | 31 Aug 2020 20:20:15 |

US3762120

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | (b) (4) Samantha Wheeler (b) (4) (b) (4) | 31 Aug 2020 20:20:15 |

US3762120

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | (b) (4) Samantha Wheeler (b) (4) (b) (4) | 31 Aug 2020 20:20:15 |

US3762120

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:43

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | (b) (4) Samantha Wheeler (b) (4) (b) (4) | 31 Aug 2020 20:20:15 |

US3762120

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:43

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | (b) (4) Samantha Wheeler (b) (4) (b) (4) | 31 Aug 2020 20:20:15 |

US3762120

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:43

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 31 Aug 2020 19:34:21 |

US3762120

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:43

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'I' | System | 31 Aug 2020 20:20:39 |

US3762120

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | (b) (4) Samantha Wheeler (b) (4) (b) (4) | 31 Aug 2020 20:20:39 |

US3762120

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:41:43

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | James Lovette (b) (4) | 03 Sep 2020 18:08:59 |

US3762120

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:43

[Condition](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Tinnitus - version MedDRA\\23.0. | Coder Import (b) (4) | 03 Sep 2020 18:11:54 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 03 Sep 2020 18:11:54 |
| Data point term sent to Coder | System | 03 Sep 2020 18:10:27 |
| User entered 'Tinnitus' | James Lovette (b) (4) | 03 Sep 2020 18:09:40 |

US3762120

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '01 Jan 2010' | (b) (4) James Lovette (b) (4) | 03 Sep 2020 18:09:40 |

US3762120

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:09:40 |

US3762120

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:43

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | James Lovette (b) (4) | 03 Sep 2020 18:09:40 |

US3762120

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | James Lovette (b) (4) | 03 Sep 2020 18:09:40 |

US3762120

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:43

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:09:40 |

US3762120

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'Jan 2010' | System | 03 Sep 2020 18:09:40 |

US3762120

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '2010' | System | 03 Sep 2020 18:09:40 |

US3762120

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered empty. | System | 03 Sep 2020 18:09:40 |

US3762120

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered empty. | System | 03 Sep 2020 18:09:40 |

US3762120

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:43

Condition

| Audit | User | Time (GMT) |
|---|------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Disability issues, PT: Corrective lens user, LLT: Corrective lens user - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 19 Sep 2020 16:35:55 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Sep 2020 16:35:55 |
| User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Disability issues, PT: Corrective lens user, LLT: Contact lens wearer - version MedDRA\\23.0. | Coder Import (b) (4) | 03 Sep 2020 18:11:53 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 03 Sep 2020 18:11:53 |
| Data point term sent to Coder | System | 03 Sep 2020 18:10:27 |
| User entered 'Glasses/Contacts' | James Lovette (b) (4) | 03 Sep 2020 18:10:13 |
| | (b) (4) | |

US3762120

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '01 Jan 1990' | James Lovette (b) (4) | 03 Sep 2020 18:10:13 |

US3762120

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:10:13 |

US3762120

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:43

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | James Lovette (b) (4) | 03 Sep 2020 18:10:13 |

US3762120

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | James Lovette (b) (4) | 03 Sep 2020 18:10:13 |

US3762120

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:43

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:10:13 |

US3762120

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'Jan 1990' | System | 03 Sep 2020 18:10:13 |

US3762120

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '1990' | System | 03 Sep 2020 18:10:13 |

US3762120

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered empty. | System | 03 Sep 2020 18:10:13 |

US3762120

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered empty. | System | 03 Sep 2020 18:10:13 |

US3762120

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:41:43

Condition

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User closed query ' Per DM CLR: Please note, stop date of MH = 31 DEC 2018. However, no procedure or treatment recorded for this condition. Review and update medical history as appropriate. Else, clarify.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 26 Oct 2020 22:20:23 |
| Query ' Per DM CLR: Please note, stop date of MH = 31 DEC 2018. However, no procedure or treatment recorded for this condition. Review and update medical history as appropriate. Else, clarify.' answered with 'not sure where the date come from but can add cataracts removal to log.' (Site from DM). | Samantha Wheeler (b) (4) (b) (4) | 20 Oct 2020 18:26:31 |
| User opened query ' Per DM CLR: Please note, stop date of MH = 31 DEC 2018. However, no procedure or treatment recorded for this condition. Review and update medical history as appropriate. Else, clarify.' (Site from DM). | (b) (4), (b) (6) | 08 Oct 2020 18:29:34 |
| User coded data point as SOC: Eye disorders, HLGT: Coder Import Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\23.0. | (b) (4) (b) (4) | 03 Sep 2020 18:12:41 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 03 Sep 2020 18:12:41 |
| Data point term sent to Coder | System | 03 Sep 2020 18:11:29 |
| User entered 'Cataracts' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:11:02 |

US3762120

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'UN UNK 2010' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 12 Oct 2020 18:14:01 |
| User entered '01 Jan 2010' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:11:02 |

US3762120

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:11:02 |

US3762120

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:41:43

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | James Lovette (b) (4) | 03 Sep 2020 18:11:02 |

US3762120

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'UN UNK 2018' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 12 Oct 2020 18:14:01 |
| User entered '31 Dec 2018' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:11:02 |

US3762120

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:41:43

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:11:02 |

US3762120

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'Jan 2010' | System | 03 Sep 2020 18:11:02 |

US3762120

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '2010' | System | 03 Sep 2020 18:11:02 |

US3762120

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'Jan 2018' | System | 12 Oct 2020 18:14:01 |
| User entered 'Dec 2018' | System | 03 Sep 2020 18:11:02 |

US3762120

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '2018' | System | 03 Sep 2020 18:11:02 |

US3762120

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:41:43

[Condition](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness, LLT: Hearing loss - version MedDRA\\23.0. | Coder Import (b) (4) | 03 Sep 2020 18:13:45 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 03 Sep 2020 18:13:45 |
| Data point term sent to Coder | System | 03 Sep 2020 18:12:32 |
| User entered 'Hearing Loss' | James Lovette (b) (4) | 03 Sep 2020 18:11:45 |

US3762120

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '01 Jan 2016' | James Lovette (b) (4) | 03 Sep 2020 18:11:45 |

US3762120

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:11:45 |

US3762120

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:41:43

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | James Lovette (b) (4) | 03 Sep 2020 18:11:45 |

US3762120

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | James Lovette (b) (4) | 03 Sep 2020 18:11:45 |

US3762120

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:41:43

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:11:45 |

US3762120

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'Jan 2016' | System | 03 Sep 2020 18:11:45 |

US3762120

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '2016' | System | 03 Sep 2020 18:11:45 |

US3762120

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered empty. | System | 03 Sep 2020 18:11:45 |

US3762120

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered empty. | System | 03 Sep 2020 18:11:45 |

US3762120

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:41:43

[Condition](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Skin cancer, LLT: Skin cancer - version MedDRA\\23.0. | Coder Import (b) (4) | 03 Sep 2020 18:14:48 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 03 Sep 2020 18:14:48 |
| Data point term sent to Coder | System | 03 Sep 2020 18:13:33 |
| User entered 'sKIN cANCER' | James Lovette (b) (4) | 03 Sep 2020 18:12:34 |

US3762120

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '01 Jan 1980' | James Lovette (b) (4) | 03 Sep 2020 18:12:34 |

US3762120

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:12:34 |

US3762120

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:41:43

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | James Lovette (b) (4) | 03 Sep 2020 18:12:34 |

US3762120

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '31 Dec 2019' | James Lovette (b) (4) | 03 Sep 2020 18:12:34 |

US3762120

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:41:43

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:12:34 |

US3762120

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'Jan 1980' | System | 03 Sep 2020 18:12:34 |

US3762120

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '1980' | System | 03 Sep 2020 18:12:34 |

US3762120

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'Dec 2019' | System | 03 Sep 2020 18:12:34 |

US3762120

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '2019' | System | 03 Sep 2020 18:12:34 |

US3762120

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:41:43

[Condition](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\\23.0. | Coder Import (b) (4) | 04 Sep 2020 08:16:37 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 04 Sep 2020 08:16:37 |
| Data point term sent to Coder | System | 03 Sep 2020 18:13:35 |
| User entered 'eXZEMA' | James Lovette (b) (4) | 03 Sep 2020 18:13:03 |
| | (b) (4) | |

US3762120

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '01 Jan 2010' | James Lovette (b) (4) | 03 Sep 2020 18:13:03 |

US3762120

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:13:03 |

US3762120

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:41:43

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | James Lovette (b) (4) | 03 Sep 2020 18:13:03 |

US3762120

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | James Lovette (b) (4) | 03 Sep 2020 18:13:03 |

US3762120

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:41:43

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:13:03 |

US3762120

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'Jan 2010' | System | 03 Sep 2020 18:13:03 |

US3762120

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '2010' | System | 03 Sep 2020 18:13:03 |

US3762120

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered empty. | System | 03 Sep 2020 18:13:03 |

US3762120

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered empty. | System | 03 Sep 2020 18:13:03 |

US3762120

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:41:43

[Condition](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Cornification and dystrophic skin disorders, HLT: Skin preneoplastic conditions NEC, PT: Actinic keratosis, LLT: Actinic keratosis - version MedDRA\\23.0. | Coder Import (b) (4) | 03 Sep 2020 20:49:50 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 03 Sep 2020 20:49:50 |
| Data point term sent to Coder | System | 03 Sep 2020 18:13:36 |
| User entered 'aCTINIC kERTATOSIS' | James Lovette (b) (4) | 03 Sep 2020 18:13:35 |

US3762120

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '01 Jan 2000' | (b) (4) James Lovette (b) (4) | 03 Sep 2020 18:13:35 |

US3762120

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:13:35 |

US3762120

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:41:43

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | James Lovette (b) (4) | 03 Sep 2020 18:13:35 |

US3762120

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | James Lovette (b) (4) | 03 Sep 2020 18:13:35 |

US3762120

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:41:43

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:13:35 |

US3762120

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'Jan 2000' | System | 03 Sep 2020 18:13:35 |

US3762120

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '2000' | System | 03 Sep 2020 18:13:35 |

US3762120

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered empty. | System | 03 Sep 2020 18:13:35 |

US3762120

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered empty. | System | 03 Sep 2020 18:13:35 |

US3762120

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:41:43

Condition

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User closed query 'Per DM CLR: Please specify the type of Arrhythmia (eg. bradyarrhythmia, supraventricular arrhythmias, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 01 Dec 2020 15:56:31 |
| User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Paroxysmal atrial fibrillation - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 29 Oct 2020 19:57:42 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 29 Oct 2020 19:57:42 |
| Data point term sent to Coder | System | 28 Oct 2020 19:23:33 |
| Query 'Per DM CLR: Please specify the type of Arrhythmia (eg. bradyarrhythmia, supraventricular arrhythmias, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'UPDATED' (Site from DM). | (b) (4), (b) (6) | 28 Oct 2020 19:23:20 |
| Coding entries removed. | (b) (4), (b) (6) | 28 Oct 2020 19:23:11 |
| User entered 'PROXIMAL ATRIAL FIBRILLATION' reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Oct 2020 19:23:11 |
| User opened query 'Per DM CLR: Please specify the type of Arrhythmia (eg. bradyarrhythmia, supraventricular arrhythmias, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM). | (b) (4), (b) (6) | 28 Oct 2020 16:35:01 |
| User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Arrhythmia, LLT: Arrhythmia - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 03 Sep 2020 21:36:44 |

US3762120

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:41:43

[Condition](#)

| Audit | User | Time (GMT) |
|---|---|--|
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. Data point term sent to Coder | Coder Import (b) (4) (b) (4) System | 03 Sep 2020 21:36:44 03 Sep 2020 18:14:41 |
| User entered 'Arrhythmia (Irregular Heartbeat)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:14:35 |

US3762120

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '01 Jan 2019' | (b) (4) James Lovette (b) (4) | 03 Sep 2020 18:14:35 |

US3762120

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:14:35 |

US3762120

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:41:43

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User closed query 'Per DM CLR: Please review response to Is the Event/Condition Ongoing? = NO. As this is a chronic condition a stop date is unexpected, please verify status of this condition and consider updating response to Is the Event/Condition Ongoing, as applicable. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 19:46:56 |
| Query 'Per DM CLR: Please review response to Is the Event/Condition Ongoing? = NO. As this is a chronic condition a stop date is unexpected, please verify status of this condition and consider updating response to Is the Event/Condition Ongoing, as applicable. ' answered with 'updated' (Site from DM). | Samantha Wheeler (b) (4) (b) (4) | 20 Jan 2021 21:00:54 |
| User opened query 'Per DM CLR: Please review response to Is the Event/Condition Ongoing? = NO. As this is a chronic condition a stop date is unexpected, please verify status of this condition and consider updating response to Is the Event/Condition Ongoing, as applicable. ' (Site from DM). | (b) (4), (b) (6) | 18 Jan 2021 05:51:16 |
| User entered 'No (N)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:14:35 |

US3762120

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '31 Dec 2019' | (b) (4) James Lovette (b) (4) | 03 Sep 2020 18:14:35 |

US3762120

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:41:43

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:14:35 |

US3762120

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'Jan 2019' | System | 03 Sep 2020 18:14:35 |

US3762120

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '2019' | System | 03 Sep 2020 18:14:35 |

US3762120

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'Dec 2019' | System | 03 Sep 2020 18:14:35 |

US3762120

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '2019' | System | 03 Sep 2020 18:14:35 |

US3762120

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:41:43

[Condition](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User coded data point as SOC: Vascular disorders, HLT: Aneurysms and artery dissections, HLT: Aortic aneurysms and dissections, PT: Aortic aneurysm, LLT: Aortic aneurysm - version MedDRA\23.0. | Coder Import (b) (4) | 03 Sep 2020 21:35:49 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 03 Sep 2020 21:35:49 |
| Data point term sent to Coder | System | 03 Sep 2020 18:15:41 |
| User entered 'Aortic Aneurism' | James Lovette (b) (4) | 03 Sep 2020 18:15:08 |

US3762120

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '01 Jan 2000' | (b) (4) James Lovette (b) (4) | 03 Sep 2020 18:15:08 |

US3762120

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:15:08 |

US3762120

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:41:43

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | (b) (4) James Lovette (b) (4) | 03 Sep 2020 18:15:08 |

US3762120

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | James Lovette (b) (4) | 03 Sep 2020 18:15:08 |

US3762120

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:41:43

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:15:08 |

US3762120

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'Jan 2000' | System | 03 Sep 2020 18:15:08 |

US3762120

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '2000' | System | 03 Sep 2020 18:15:08 |

US3762120

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered empty. | System | 03 Sep 2020 18:15:08 |

US3762120

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered empty. | System | 03 Sep 2020 18:15:08 |

US3762120

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:41:43

[Condition](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0. | Coder Import (b) (4) | 03 Sep 2020 18:17:46 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 03 Sep 2020 18:17:46 |
| Data point term sent to Coder | System | 03 Sep 2020 18:16:44 |
| User entered 'Heartburn' | James Lovette (b) (4) | 03 Sep 2020 18:15:56 |

US3762120

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '01 Jan 2015' | James Lovette (b) (4) | 03 Sep 2020 18:15:56 |

US3762120

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:15:56 |

US3762120

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:41:43

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | James Lovette (b) (4) | 03 Sep 2020 18:15:56 |

US3762120

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | James Lovette (b) (4) | 03 Sep 2020 18:15:56 |

US3762120

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:41:43

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:15:56 |

US3762120

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'Jan 2015' | System | 03 Sep 2020 18:15:56 |

US3762120

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '2015' | System | 03 Sep 2020 18:15:56 |

US3762120

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered empty. | System | 03 Sep 2020 18:15:56 |

US3762120

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered empty. | System | 03 Sep 2020 18:15:56 |

US3762120

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:41:43

Condition

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\\23.0. | Coder Import (b) (4) | 03 Sep 2020 18:17:47 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 03 Sep 2020 18:17:47 |
| Data point term sent to Coder | System | 03 Sep 2020 18:16:46 |
| User entered 'Kidney Stones' | James Lovette (b) (4) | 03 Sep 2020 18:16:36 |

US3762120

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '01 Jan 1967' | James Lovette (b) (4) | 03 Sep 2020 18:16:36 |

US3762120

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:16:36 |

US3762120

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:41:43

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | James Lovette (b) (4) | 03 Sep 2020 18:16:36 |

US3762120

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '31 Dec 1967' | James Lovette (b) (4) | 03 Sep 2020 18:16:36 |

US3762120

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:41:43

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:16:36 |

US3762120

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'Jan 1967' | System | 03 Sep 2020 18:16:36 |

US3762120

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '1967' | System | 03 Sep 2020 18:16:36 |

US3762120

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'Dec 1967' | System | 03 Sep 2020 18:16:36 |

US3762120

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '1967' | System | 03 Sep 2020 18:16:36 |

US3762120

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:41:43

[Condition](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User coded data point as SOC: Social circumstances, HLT: Lifestyle issues, HLT: Social issues NEC, PT: Blood donor, LLT: Blood donor - version MedDRA\\23.0. | Coder Import (b) (4) | 03 Sep 2020 18:19:43 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 03 Sep 2020 18:19:43 |
| Data point term sent to Coder | System | 03 Sep 2020 18:18:53 |
| User entered 'Frequent Blood/Plasma Donor' | James Lovette (b) (4) | 03 Sep 2020 18:18:17 |

US3762120

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '01 Jan 2016' | (b) (4) James Lovette (b) (4) | 03 Sep 2020 18:18:17 |

US3762120

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:18:17 |

US3762120

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:41:43

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | James Lovette (b) (4) | 03 Sep 2020 18:18:17 |

US3762120

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | James Lovette (b) (4) | 03 Sep 2020 18:18:17 |

US3762120

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:41:43

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:18:17 |

US3762120

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'Jan 2016' | System | 03 Sep 2020 18:18:17 |

US3762120

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '2016' | System | 03 Sep 2020 18:18:17 |

US3762120

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered empty. | System | 03 Sep 2020 18:18:17 |

US3762120

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered empty. | System | 03 Sep 2020 18:18:17 |

US3762120

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:41:43

[Condition](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| 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: BPH - version MedDRA\\23.0. | Coder Import (b) (4) | 08 Sep 2020 13:17:48 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 08 Sep 2020 13:17:48 |
| Data point term sent to Coder | System | 03 Sep 2020 18:19:54 |
| User entered 'Prostate Issues (BPH, enlarged)' | James Lovette (b) (4) | 03 Sep 2020 18:19:16 |

US3762120

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '01 Jan 2016' | James Lovette (b) (4) | 03 Sep 2020 18:19:16 |

US3762120

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:19:16 |

US3762120

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:41:43

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 03 Sep 2020 18:22:05 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | James Lovette (b) (4) | 03 Sep 2020 18:22:05 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| User entered empty. | System | 03 Sep 2020 18:19:16 |
| | James Lovette (b) (4) | 03 Sep 2020 18:19:16 |
| | (b) (4) | |

US3762120

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | James Lovette (b) (4) | 03 Sep 2020 18:19:16 |

US3762120

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:41:43

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:19:16 |

US3762120

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'Jan 2016' | System | 03 Sep 2020 18:19:16 |

US3762120

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '2016' | System | 03 Sep 2020 18:19:16 |

US3762120

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered empty. | System | 03 Sep 2020 18:19:16 |

US3762120

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered empty. | System | 03 Sep 2020 18:19:16 |

US3762120

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:41:43

[Condition](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Testicular neoplasms malignant, PT: Seminoma, LLT: Seminoma - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Sep 2020 15:59:53 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Sep 2020 15:59:53 |
| Data point term sent to Coder | System | 03 Sep 2020 18:21:01 |
| User entered 'Seminoma, left testicle' | James Lovette (b) (4) | 03 Sep 2020 18:20:50 |

US3762120

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '01 Jan 1989' | (b) (4) James Lovette (b) (4) | 03 Sep 2020 18:20:50 |

US3762120

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:20:50 |

US3762120

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:41:43

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | James Lovette (b) (4) | 03 Sep 2020 18:20:50 |

US3762120

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '31 Dec 1989' | James Lovette (b) (4) | 03 Sep 2020 18:20:50 |

US3762120

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:41:43

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:20:50 |

US3762120

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'Jan 1989' | System | 03 Sep 2020 18:20:50 |

US3762120

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '1989' | System | 03 Sep 2020 18:20:50 |

US3762120

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'Dec 1989' | System | 03 Sep 2020 18:20:50 |

US3762120

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '1989' | System | 03 Sep 2020 18:20:50 |

US3762120

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:41:43

[Condition](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Skin cancer, LLT: Skin cancer - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 04 Sep 2020 16:21:44 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 04 Sep 2020 16:21:44 |
| Data point term sent to Coder | System | 03 Sep 2020 18:22:02 |
| User entered 'Some type of skin cancer' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:21:35 |

US3762120

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '01 Jan 1980' | James Lovette (b) (4) | 03 Sep 2020 18:21:35 |

US3762120

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:21:35 |

US3762120

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:41:43

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | James Lovette (b) (4) | 03 Sep 2020 18:21:35 |

US3762120

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '31 Dec 1980' | (b) (4) James Lovette (b) (4) | 03 Sep 2020 18:21:35 |

US3762120

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:41:43

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:21:35 |

US3762120

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'Jan 1980' | System | 03 Sep 2020 18:21:35 |

US3762120

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '1980' | System | 03 Sep 2020 18:21:35 |

US3762120

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'Dec 1980' | System | 03 Sep 2020 18:21:35 |

US3762120

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '1980' | System | 03 Sep 2020 18:21:35 |

US3762120

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:41:43

[Condition](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' canceled (Site from DM). | (b) (4) (b) (4), (b) (6) | 27 Oct 2020 06:33:41 |
| User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM). | (b) (4), (b) (6) | 27 Oct 2020 06:33:06 |
| User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Paroxysmal atrial fibrillation - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 06 Oct 2020 19:24:16 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 06 Oct 2020 19:24:16 |
| Data point term sent to Coder | System | 06 Oct 2020 19:23:05 |
| User entered 'proximal atrial fibrillation' | Samantha Wheeler (b) (4) (b) (4) | 06 Oct 2020 19:22:44 |

US3762120

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'un UNK 2019' | (b) (4) Samantha Wheeler (b) (4) (b) (4) | 06 Oct 2020 19:22:44 |

US3762120

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | (b) (4) Samantha Wheeler (b) (4) (b) (4) | 06 Oct 2020 19:22:44 |

US3762120

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:41:43

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | (b) (4) Samantha Wheeler (b) (4) (b) (4) | 06 Oct 2020 19:22:44 |

US3762120

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | (b) (4) Samantha Wheeler (b) (4) (b) (4) | 06 Oct 2020 19:22:44 |

US3762120

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:41:43

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | (b) (4) Samantha Wheeler (b) (4) (b) (4) | 06 Oct 2020 19:22:44 |

US3762120

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'Jan 2019' | System | 06 Oct 2020 19:22:44 |

US3762120

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '2019' | System | 06 Oct 2020 19:22:44 |

US3762120

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered empty. | System | 06 Oct 2020 19:22:44 |

US3762120

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered empty. | System | 06 Oct 2020 19:22:44 |

US3762120

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:41:43

Condition

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract extraction - version MedDRA\\23.0. | Coder Import (b) (4) | 20 Oct 2020 18:28:37 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 20 Oct 2020 18:28:37 |
| Data point term sent to Coder | System | 20 Oct 2020 18:27:42 |
| User entered 'cataract removal' | Samantha Wheeler (b) (4) | 20 Oct 2020 18:26:50 |

US3762120

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'un UNK 2018' | (b) (4) Samantha Wheeler (b) (4) | 20 Oct 2020 18:26:50 |

US3762120

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | (b) (4) Samantha Wheeler (b) (4) (b) (4) | 20 Oct 2020 18:26:50 |

US3762120

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:41:43

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | (b) (4) Samantha Wheeler (b) (4) | 20 Oct 2020 18:26:50 |

US3762120

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'un UNK 2018' | (b) (4) Samantha Wheeler (b) (4) (b) (4) | 20 Oct 2020 18:26:50 |

US3762120

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:41:43

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | (b) (4) Samantha Wheeler (b) (4) (b) (4) | 20 Oct 2020 18:26:50 |

US3762120

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'Jan 2018' | System | 20 Oct 2020 18:26:50 |

US3762120

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '2018' | System | 20 Oct 2020 18:26:50 |

US3762120

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'Jan 2018' | System | 20 Oct 2020 18:26:50 |

US3762120

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '2018' | System | 20 Oct 2020 18:26:50 |

US3762120

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | James Lovette (b) (4) | 03 Sep 2020 18:24:26 |

US3762120

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '31 Aug 2020' | James Lovette (b) (4) | 03 Sep 2020 18:24:26 |

US3762120

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '15:15' | James Lovette (b) (4) | 03 Sep 2020 18:24:26 |

US3762120

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '31 Aug 2020 15:15' | System | 03 Sep 2020 18:24:26 |

US3762120

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Height \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '172.5' cm | (b) (4) James Lovette (b) (4) | 03 Sep 2020 18:24:26 |
| DataPoint set to visible. | (b) (4) System | 31 Aug 2020 20:20:39 |

US3762120

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Weight \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '176' lb | (b) (4) James Lovette (b) (4) | 03 Sep 2020 18:24:26 |
| DataPoint set to visible. | (b) (4) System | 31 Aug 2020 20:20:39 |

US3762120

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[BMI \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered '26.88511' | System | 03 Sep 2020 18:24:26 |
| DataPoint set to visible. | System | 31 Aug 2020 20:20:39 |

US3762120

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'kg/m2' | System | 03 Sep 2020 18:24:26 |
| DataPoint set to visible. | System | 31 Aug 2020 20:20:39 |

US3762120

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered missing code ND - Not Done. | (b) (4) James Lovette (b) (4) | 03 Sep 2020 18:24:26 |

US3762120

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | (b) (4) James Lovette (b) (4) | 03 Sep 2020 18:24:26 |

US3762120

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | James Lovette (b) (4) | 03 Sep 2020 18:24:26 |

US3762120

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered missing code ND - Not Done. | (b) (4) James Lovette (b) (4) | 03 Sep 2020 18:24:26 |

US3762120

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'bpm' | System | 03 Sep 2020 18:24:26 |

US3762120

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered missing code ND - Not Done. | James Lovette (b) (4) | 03 Sep 2020 18:24:26 |

US3762120

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'breaths/min' | System | 03 Sep 2020 18:24:26 |

US3762120

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered missing code ND - Not Done. | (b) (4) James Lovette (b) (4) | 03 Sep 2020 18:24:26 |

US3762120

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'mmHg' | System | 03 Sep 2020 18:24:26 |

US3762120

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered missing code ND - Not Done. | (b) (4) James Lovette (b) (4) | 03 Sep 2020 18:24:26 |

US3762120

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User entered 'mmHg' | System | 03 Sep 2020 18:24:26 |

US3762120

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |

US3762120

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |

US3762120

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:43

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | James Lovette (b) (4) | 03 Sep 2020 18:24:48 |

US3762120

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:43

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '31 Aug 2020' | James Lovette (b) (4) | 03 Sep 2020 18:24:48 |

US3762120

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:43

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | (b) (4) James Lovette (b) (4) | 03 Sep 2020 18:26:46 |

US3762120

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:43

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | (b) (4) James Lovette (b) (4) | 03 Sep 2020 18:26:46 |

US3762120

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:43

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) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | James Lovette (b) (4) | 03 Sep 2020 18:26:46 |

US3762120

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:43

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) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | James Lovette (b) (4) | 03 Sep 2020 18:26:46 |

US3762120

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:43

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | James Lovette (b) (4) | 03 Sep 2020 18:26:46 |

US3762120

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:43

[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) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | James Lovette (b) (4) | 03 Sep 2020 18:26:46 |

US3762120

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:43

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) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | James Lovette (b) (4) | 03 Sep 2020 18:26:46 |

US3762120

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:43

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) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | James Lovette (b) (4) | 03 Sep 2020 18:26:46 |

US3762120

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:43

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) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | James Lovette (b) (4) | 03 Sep 2020 18:26:46 |

US3762120

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:43

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) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | James Lovette (b) (4) | 03 Sep 2020 18:26:46 |

US3762120

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:43

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) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | James Lovette (b) (4) | 03 Sep 2020 18:26:46 |

US3762120

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:43

Other

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | James Lovette (b) (4) | 03 Sep 2020 18:26:46 |

US3762120

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:43

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | James Lovette (b) (4) | 03 Sep 2020 18:26:46 |

US3762120

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:43

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:26:46 |

US3762120

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:43

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:26:46 |

US3762120

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:43

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) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:26:46 |

US3762120

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:43

[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) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | (b) (4) James Lovette (b) (4) | 03 Sep 2020 18:26:46 |

US3762120

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:43

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) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:26:46 |

US3762120

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:43

Resides in a single family home (i.e., detached housing)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '0' | James Lovette (b) (4) | 03 Sep 2020 18:26:46 |

US3762120

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:43

Other

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'I' | James Lovette (b) (4) | 03 Sep 2020 18:26:46 |

US3762120

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:43

[Specify](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:16:37 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Participant interacts with 5 or more people in typical work day.' | (b) (4) James Lovette (b) (4) | 03 Sep 2020 18:26:46 |

US3762120

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:41:43

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | Samantha Wheeler (b) (4) | 31 Aug 2020 20:20:51 |

US3762120

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:41:43

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 31AUG2020 is reported under Visit 1 Day 1visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 10:17:45 |
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 31AUG2020 is reported under Visit 1 Day 1visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'Samples received ' (Site from DM). | (b) (4), (b) (6) | 26 Oct 2020 20:02:31 |
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 31AUG2020 is reported under Visit 1 Day 1visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM). | (b) (4), (b) (6) | 21 Oct 2020 15:15:10 |
| User entered '31 Aug 2020' | Samantha Wheeler (b) (4) (b) (4) | 31 Aug 2020 20:20:51 |

US3762120

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:41:43

[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 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Clinic (Clinic)' | Samantha Wheeler (b) (4) | 31 Aug 2020 20:20:51 |

US3762120

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:41:43

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'VISIT1' | System | 31 Aug 2020 20:20:51 |

US3762120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '31 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 31 Aug 2020 20:09:53 |

US3762120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:43

[What was the participant's randomization number?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '189264' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 31 Aug 2020 20:09:53 |

US3762120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:43

[In what Cohort was the participant enrolled?](#)

| Audit | User | Time (GMT) |
|-------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '>=65 years (3)' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 31 Aug 2020 20:09:53 |

US3762120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:43

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 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | James Lovette (b) (4) | 03 Sep 2020 18:29:35 |

US3762120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:43

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 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | James Lovette (b) (4) | 03 Sep 2020 18:29:35 |

US3762120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:43

Severe obesity (body mass index > or = 40kg/m2)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | James Lovette (b) (4) | 03 Sep 2020 18:29:35 |

US3762120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:43

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | James Lovette (b) (4) | 03 Sep 2020 18:29:35 |

US3762120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:43

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | James Lovette (b) (4) | 03 Sep 2020 18:29:35 |

US3762120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:43

[Human Immunodeficiency Virus \(HIV\) infection](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | James Lovette (b) (4) | 22 Sep 2020 19:56:23 |
| Amendment Manager: DataPoint set to visible. | System | 19 Sep 2020 08:49:02 |
| Amendment Manager inserted this DataPoint. | System | 19 Sep 2020 08:49:00 |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:43

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered missing code ND - Not Done. | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:43

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered missing code ND - Not Done. | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:43

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered missing code ND - Not Done. | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:43

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered missing code ND - Not Done. | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User accepted default value 'Pre-Dose (PREDOSE)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:31:44 |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 03 Sep 2020 18:37:41 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | James Lovette (b) (4) | 03 Sep 2020 18:37:41 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| User entered empty. | System | 03 Sep 2020 18:31:44 |
| | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |
| | (b) (4) | |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '31 Aug 2020' reason for change: Data Entry Error | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:37:41 |
| User entered empty. | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |
| | (b) (4) | |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '15:15' reason for change: Data Entry Error | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:37:41 |
| User entered empty. | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |
| | (b) (4) | |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered '31 Aug 2020 15:15' | System | 03 Sep 2020 18:37:41 |
| User entered empty. | System | 03 Sep 2020 18:31:44 |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '98.3' F reason for change: Data Entry Error | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:37:41 |
| User entered empty. | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |
| | (b) (4) | |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:37:41 |
| User entered empty. | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |
| | (b) (4) | |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '48' reason for change: Data Entry Error | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:37:41 |
| User entered empty. | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |
| | (b) (4) | |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'bpm' | System | 03 Sep 2020 18:37:41 |
| User entered empty. | System | 03 Sep 2020 18:31:44 |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '14' reason for change: Data Entry Error | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:37:41 |
| User entered empty. | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |
| | (b) (4) | |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'breaths/min' | System | 03 Sep 2020 18:37:41 |
| User entered empty. | System | 03 Sep 2020 18:31:44 |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '132' reason for change: Data Entry Error | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:37:41 |
| User entered empty. | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |
| | (b) (4) | |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'mmHg' | System | 03 Sep 2020 18:37:41 |
| User entered empty. | System | 03 Sep 2020 18:31:44 |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '68' reason for change: Data Entry Error | James Lovette (b) (4) | 03 Sep 2020 18:37:41 |
| User entered empty. | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'mmHg' | System | 03 Sep 2020 18:37:41 |
| User entered empty. | System | 03 Sep 2020 18:31:44 |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:43

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered missing code ND - Not Done. | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:43

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered missing code ND - Not Done. | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User accepted default value 'Post-Dose (POSTDOSE)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:31:44 |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 03 Sep 2020 18:39:07 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | James Lovette (b) (4) | 03 Sep 2020 18:39:07 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| User entered empty. | System | 03 Sep 2020 18:31:44 |
| | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '31 Aug 2020' reason for change: Data Entry Error | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:39:07 |
| User entered empty. | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '16:50' reason for change: Data Entry Error | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:39:07 |
| User entered empty. | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |
| | (b) (4) | |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered '31 Aug 2020 16:50' | System | 03 Sep 2020 18:39:07 |
| User entered empty. | System | 03 Sep 2020 18:31:44 |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '96.8' F reason for change: Data Entry Error | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:39:07 |
| User entered empty. | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |
| | (b) (4) | |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:39:07 |
| User entered empty. | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |
| | (b) (4) | |

US3762120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '48' reason for change: Data Entry Error | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:39:07 |
| User entered empty. | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'bpm' | System | 03 Sep 2020 18:39:07 |
| User entered empty. | System | 03 Sep 2020 18:31:44 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '16' reason for change: Data Entry Error | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:39:07 |
| User entered empty. | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'breaths/min' | System | 03 Sep 2020 18:39:07 |
| User entered empty. | System | 03 Sep 2020 18:31:44 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '128' reason for change: Data Entry Error | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:39:07 |
| User entered empty. | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'mmHg' | System | 03 Sep 2020 18:39:07 |
| User entered empty. | System | 03 Sep 2020 18:31:44 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '67' reason for change: Data Entry Error | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:39:07 |
| User entered empty. | (b) (4) | |
| | James Lovette (b) (4) | 03 Sep 2020 18:31:44 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'mmHg' | System | 03 Sep 2020 18:39:07 |
| User entered empty. | System | 03 Sep 2020 18:31:44 |

US3762120

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:43

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | James Lovette (b) (4) | 03 Sep 2020 18:50:19 |

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:43

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | James Lovette (b) (4) | 03 Sep 2020 18:50:19 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:43

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | (b) (4) Samantha Wheeler (b) (4) | 31 Aug 2020 20:22:26 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:43

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | Samantha Wheeler (b) (4) | 31 Aug 2020 20:22:26 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:43

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 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | Samantha Wheeler (b) (4) | 31 Aug 2020 20:22:26 |

US3762120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:43

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 31 Aug 2020 20:22:26 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:43

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '31 Aug 2020' | Samantha Wheeler (b) (4) | 31 Aug 2020 20:22:26 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:43

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '16:18' | Samantha Wheeler (b) (4) | 31 Aug 2020 20:22:26 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:43

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered '31 Aug 2020 16:18' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:43

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Left Arm (LEFT ARM)' | Samantha Wheeler (b) (4) | 31 Aug 2020 20:22:26 |

US3762120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:43

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'ONCE' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:43

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'INTRAMUSCULAR' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:43

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 31Aug2020 is reported under Visit 1 Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 09:58:48 |
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 31Aug2020 is reported under Visit 1 Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'UPDATED' (Site from DM). | (b) (4), (b) (6) | 03 Nov 2020 14:01:51 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 03 Nov 2020 14:01:44 |
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 31Aug2020 is reported under Visit 1 Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM). | (b) (4), (b) (6) | 31 Oct 2020 13:37:42 |
| User entered 'No (N)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:39:53 |

US3762120

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:43

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 03 Nov 2020 14:02:50 |
| User entered '31 Aug 2020' reason for change: Data Entry Error | System | 03 Nov 2020 14:02:50 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 03 Nov 2020 14:01:44 |
| User entered empty. | James Lovette (b) (4) | 03 Sep 2020 18:39:53 |
| | (b) (4) | |

US3762120

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:43

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 03 Nov 2020 14:02:50 |
| User entered '3:58' reason for change: Data Entry Error | System | 03 Nov 2020 14:02:50 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 03 Nov 2020 14:01:44 |
| User entered empty. | James Lovette (b) (4) | 03 Sep 2020 18:39:53 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:43

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered '31 Aug 2020 3:58' | System | 03 Nov 2020 14:02:50 |
| User entered empty. | System | 03 Sep 2020 18:39:53 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:41:43

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '31 Aug 2020' | James Lovette (b) (4) | 03 Sep 2020 18:40:35 |

US3762120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:41:43

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:40:35 |

US3762120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:41:43

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | James Lovette (b) (4) | 03 Sep 2020 18:40:35 |

US3762120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:41:43

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '16:04' | James Lovette (b) (4) | 03 Sep 2020 18:40:35 |

US3762120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:41:43

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered '31 Aug 2020 16:04' | System | 03 Sep 2020 18:40:35 |

US3762120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:41:43

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | James Lovette (b) (4) | 03 Sep 2020 18:40:35 |

US3762120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:41:43

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | James Lovette (b) (4) | 03 Sep 2020 18:40:35 |

US3762120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:41:43

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | James Lovette (b) (4) | 03 Sep 2020 18:40:35 |

US3762120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:41:43

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered empty. | System | 03 Sep 2020 18:40:35 |

US3762120

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | James Lovette (b) (4) | 03 Sep 2020 18:40:44 |

US3762120

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'I' | System | 03 Sep 2020 18:40:44 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-08-31T16:47:41', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '43bf6eb7-8417-4cc3-b27b-f1d84d8ce73a' User entered 'Yes (Y)' | System | 31 Aug 2020 20:49:10 |
| | System | 31 Aug 2020 20:49:10 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-08-31T16:47:52', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '43bf6eb7-8417-4cc3-b27b-f1d84d8ce73a' User entered '96.8' | System | 31 Aug 2020 20:49:10 |
| | System | 31 Aug 2020 20:49:10 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-08-31T16:47:56', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '43bf6eb7-8417-4cc3-b27b-f1d84d8ce73a' User entered 'No (N)' | System | 31 Aug 2020 20:49:10 |
| | System | 31 Aug 2020 20:49:10 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-08-31T16:48:03', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '43bf6eb7-8417-4cc3-b27b-f1d84d8ce73a' User entered '31 Aug 2020 16:48' | System | 31 Aug 2020 20:49:10 |
| | System | 31 Aug 2020 20:49:10 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '31 Aug 2020 16:38' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '31 Aug 2020 19:08' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 1, after vaccination (at home)' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| | | |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| | | |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| | | |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| | | |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| | | |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| | | |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '31 Aug 2020 20:03' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '01 Sep 2020 11:59' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 2' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:43

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-01T18:46:23', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '489367b1-c7a2-46dd-a82a-e80ee3185198' User entered 'Yes (Y)' | System | 01 Sep 2020 22:46:54 |
| | System | 01 Sep 2020 22:46:54 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:43

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-01T18:46:33', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '489367b1-c7a2-46dd-a82a-e80ee3185198' User entered '97.7' | System | 01 Sep 2020 22:46:54 |
| | System | 01 Sep 2020 22:46:54 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-01T18:46:38', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '489367b1-c7a2-46dd-a82a-e80ee3185198' | System | 01 Sep 2020 22:46:54 |
| User entered 'No (N)' | System | 01 Sep 2020 22:46:54 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-01T18:46:50', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '489367b1-c7a2-46dd-a82a-e80ee3185198' User entered '01 Sep 2020 18:46' | System | 01 Sep 2020 22:46:54 |
| | System | 01 Sep 2020 22:46:54 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '01 Sep 2020 12:00' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '02 Sep 2020 11:59' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 3' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:43

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-02T17:53:51', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '74d951f8-925f-4a2c-a061-dc205c8a93d6' User entered 'Yes (Y)' | System | 02 Sep 2020 21:54:20 |
| | System | 02 Sep 2020 21:54:20 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:43

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-02T17:54:02', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '74d951f8-925f-4a2c-a061-dc205c8a93d6' User entered '98.7' | System | 02 Sep 2020 21:54:20 |
| | System | 02 Sep 2020 21:54:20 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-02T17:54:05', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '74d951f8-925f-4a2c-a061-dc205c8a93d6' | System | 02 Sep 2020 21:54:20 |
| User entered 'No (N)' | System | 02 Sep 2020 21:54:20 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-02T17:54:18', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '74d951f8-925f-4a2c-a061-dc205c8a93d6' User entered '02 Sep 2020 17:54' | System | 02 Sep 2020 21:54:20 |
| | System | 02 Sep 2020 21:54:20 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '02 Sep 2020 12:00' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '03 Sep 2020 11:59' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 4' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:43

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-03T13:03:46', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'd3da438a-fb6b-4e8d-a696-5365bfa2b9fa' User entered 'Yes (Y)' | System | 03 Sep 2020 17:04:08 |
| | System | 03 Sep 2020 17:04:08 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:43

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-03T13:03:52', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'd3da438a-fb6b-4e8d-a696-5365bfa2b9fa' User entered '97.4' | System | 03 Sep 2020 17:04:08 |
| | System | 03 Sep 2020 17:04:08 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-03T13:03:55', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'd3da438a-fb6b-4e8d-a696-5365bfa2b9fa' | System | 03 Sep 2020 17:04:08 |
| User entered 'No (N)' | System | 03 Sep 2020 17:04:08 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-03T13:04:04', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'd3da438a-fb6b-4e8d-a696-5365bfa2b9fa' User entered '03 Sep 2020 13:04' | System | 03 Sep 2020 17:04:08 |
| | System | 03 Sep 2020 17:04:08 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '03 Sep 2020 12:00' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '04 Sep 2020 11:59' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 5' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:43

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-04T13:17:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '148a7cf4-2344-40c3-9cdc-2e384d1eea17' User entered 'Yes (Y)' | System | 04 Sep 2020 17:17:21 |
| | System | 04 Sep 2020 17:17:21 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:43

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-04T13:17:08', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '148a7cf4-2344-40c3-9cdc-2e384d1eea17' User entered '97.7' | System | 04 Sep 2020 17:17:21 |
| | System | 04 Sep 2020 17:17:21 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-04T13:17:11', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '148a7cf4-2344-40c3-9cdc-2e384d1eea17' | System | 04 Sep 2020 17:17:21 |
| User entered 'No (N)' | System | 04 Sep 2020 17:17:21 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-04T13:17:17', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '148a7cf4-2344-40c3-9cdc-2e384d1eea17' User entered '04 Sep 2020 13:17' | System | 04 Sep 2020 17:17:21 |
| | System | 04 Sep 2020 17:17:21 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '04 Sep 2020 12:00' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '05 Sep 2020 11:59' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 6' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:43

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-05T13:14:24', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '1268de98-fae9-4319-8c6e-c9d87915bdd8' User entered 'Yes (Y)' | System | 05 Sep 2020 17:14:52 |
| | System | 05 Sep 2020 17:14:52 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:43

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-05T13:14:33', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '1268de98-fae9-4319-8c6e-c9d87915bdd8' User entered '98.3' | System | 05 Sep 2020 17:14:52 |
| | System | 05 Sep 2020 17:14:52 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-05T13:14:38', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '1268de98-fae9-4319-8c6e-c9d87915bdd8' User entered 'No (N)' | System | 05 Sep 2020 17:14:52 |
| | System | 05 Sep 2020 17:14:52 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-05T13:14:49', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '1268de98-fae9-4319-8c6e-c9d87915bdd8' User entered '05 Sep 2020 13:14' | System | 05 Sep 2020 17:14:52 |
| | System | 05 Sep 2020 17:14:52 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '05 Sep 2020 12:00' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '06 Sep 2020 11:59' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 7' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:43

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-06T15:05:11', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '7ffdc58d-9833-4662-925f-50c9067fe815' | System | 06 Sep 2020 19:05:39 |
| User entered 'Yes (Y)' | System | 06 Sep 2020 19:05:39 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:43

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-06T15:05:19', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '7ffdc58d-9833-4662-925f-50c9067fe815' User entered '97.2' | System | 06 Sep 2020 19:05:39 |
| | System | 06 Sep 2020 19:05:39 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-06T15:05:30', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '7ffdc58d-9833-4662-925f-50c9067fe815' | System | 06 Sep 2020 19:05:39 |
| User entered 'No (N)' | System | 06 Sep 2020 19:05:39 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-06T15:05:35', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '7ffdc58d-9833-4662-925f-50c9067fe815' | System | 06 Sep 2020 19:05:39 |
| User entered '06 Sep 2020 15:05' | System | 06 Sep 2020 19:05:39 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '06 Sep 2020 12:00' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '07 Sep 2020 11:59' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-08-31T16:48:20', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '8a9264c8-66e6-4a67-9a5e-56d6ff2420b0' User entered 'None (1)' | System | 31 Aug 2020 20:51:20 |
| | System | 31 Aug 2020 20:51:20 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-08-31T16:48:36', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '8a9264c8-66e6-4a67-9a5e-56d6ff2420b0' User entered 'No (N)' | System | 31 Aug 2020 20:51:20 |
| | System | 31 Aug 2020 20:51:20 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-08-31T16:48:55', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '8a9264c8-66e6-4a67-9a5e-56d6ff2420b0' User entered 'No (N)' | System | 31 Aug 2020 20:51:20 |
| | System | 31 Aug 2020 20:51:20 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-08-31T16:48:59', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '8a9264c8-66e6-4a67-9a5e-56d6ff2420b0' User entered 'None (1)' | System | 31 Aug 2020 20:51:20 |
| | System | 31 Aug 2020 20:51:20 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-08-31T16:49:05', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '8a9264c8-66e6-4a67-9a5e-56d6ff2420b0' User entered '31 Aug 2020 16:49' | System | 31 Aug 2020 20:51:20 |
| | System | 31 Aug 2020 20:51:20 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '31 Aug 2020 16:38' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '31 Aug 2020 19:08' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 1, after vaccination (at home)' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| | | |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| | | |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

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) | 05 Mar 2021 02:10:43 |
| | | |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| | | |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

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) | 05 Mar 2021 02:10:43 |
| | | |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| | | |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| | | |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '31 Aug 2020 20:03' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '01 Sep 2020 11:59' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 2' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-01T18:47:03', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f267ff19-d51c-4717-a021-7951d2b70d49' | System | 01 Sep 2020 22:50:26 |
| User entered 'Does not interfere with activity (2)' | System | 01 Sep 2020 22:50:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:43

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-01T18:48:24', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f267ff19-d51c-4717-a021-7951d2b70d49' | System | 01 Sep 2020 22:50:26 |
| User entered 'Yes (Y)' | System | 01 Sep 2020 22:50:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:43

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) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-01T18:50:09', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f267ff19-d51c-4717-a021-7951d2b70d49' User entered '4' | System | 01 Sep 2020 22:50:26 |
| | System | 01 Sep 2020 22:50:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-01T18:48:34', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f267ff19-d51c-4717-a021-7951d2b70d49' | System | 01 Sep 2020 22:50:26 |
| User entered 'Yes (Y)' | System | 01 Sep 2020 22:50:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:43

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) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-01T18:49:46', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f267ff19-d51c-4717-a021-7951d2b70d49' User entered '6' | System | 01 Sep 2020 22:50:26 |
| | System | 01 Sep 2020 22:50:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-01T18:49:53', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f267ff19-d51c-4717-a021-7951d2b70d49' | System | 01 Sep 2020 22:50:26 |
| User entered 'None (1)' | System | 01 Sep 2020 22:50:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-01T18:50:25', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f267ff19-d51c-4717-a021-7951d2b70d49' | System | 01 Sep 2020 22:50:26 |
| User entered '01 Sep 2020 18:50' | System | 01 Sep 2020 22:50:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '01 Sep 2020 12:00' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '02 Sep 2020 11:59' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 3' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-02T17:54:33', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f06b19ca-df12-41c2-8932-c03007bed571' User entered 'Does not interfere with activity (2)' | System | 02 Sep 2020 21:56:38 |
| | System | 02 Sep 2020 21:56:38 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:43

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-02T17:54:47', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f06b19ca-df12-41c2-8932-c03007bed571' User entered 'Yes (Y)' | System | 02 Sep 2020 21:56:38 |
| | System | 02 Sep 2020 21:56:38 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:43

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) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-02T17:55:17', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f06b19ca-df12-41c2-8932-c03007bed571' User entered '1' | System | 02 Sep 2020 21:56:38 |
| | System | 02 Sep 2020 21:56:38 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-02T17:55:25', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f06b19ca-df12-41c2-8932-c03007bed571' User entered 'Yes (Y)' | System | 02 Sep 2020 21:56:38 |
| | System | 02 Sep 2020 21:56:38 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:43

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) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-02T17:55:54', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f06b19ca-df12-41c2-8932-c03007bed571' User entered '3' | System | 02 Sep 2020 21:56:38 |
| | System | 02 Sep 2020 21:56:38 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-02T17:56:27', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f06b19ca-df12-41c2-8932-c03007bed571' User entered 'None (1)' | System | 02 Sep 2020 21:56:38 |
| | System | 02 Sep 2020 21:56:38 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-02T17:56:37', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f06b19ca-df12-41c2-8932-c03007bed571' User entered '02 Sep 2020 17:56' | System | 02 Sep 2020 21:56:38 |
| | System | 02 Sep 2020 21:56:38 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '02 Sep 2020 12:00' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '03 Sep 2020 11:59' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 4' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-03T13:04:11', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '340465c7-4e79-4092-b76b-bd263d7a8b1e' | System | 03 Sep 2020 17:05:38 |
| User entered 'Does not interfere with activity (2)' | System | 03 Sep 2020 17:05:38 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:43

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-03T13:04:14', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '340465c7-4e79-4092-b76b-bd263d7a8b1e' User entered 'No (N)' | System | 03 Sep 2020 17:05:38 |
| | System | 03 Sep 2020 17:05:38 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-03T13:04:18', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '340465c7-4e79-4092-b76b-bd263d7a8b1e' User entered 'Yes (Y)' | System | 03 Sep 2020 17:05:38 |
| | System | 03 Sep 2020 17:05:38 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:43

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) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-03T13:05:23', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '340465c7-4e79-4092-b76b-bd263d7a8b1e' User entered '4' | System | 03 Sep 2020 17:05:38 |
| | System | 03 Sep 2020 17:05:38 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-03T13:04:40', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '340465c7-4e79-4092-b76b-bd263d7a8b1e' User entered 'None (1)' | System | 03 Sep 2020 17:05:38 |
| | System | 03 Sep 2020 17:05:38 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-03T13:05:35', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '340465c7-4e79-4092-b76b-bd263d7a8b1e' User entered '03 Sep 2020 13:05' | System | 03 Sep 2020 17:05:38 |
| | System | 03 Sep 2020 17:05:38 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '03 Sep 2020 12:00' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '04 Sep 2020 11:59' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 5' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-04T13:17:22', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '0671671f-3582-40f6-9a46-4d014d1ed287' | System | 04 Sep 2020 17:17:55 |
| User entered 'None (1)' | System | 04 Sep 2020 17:17:55 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:43

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-04T13:17:25', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '0671671f-3582-40f6-9a46-4d014d1ed287' User entered 'No (N)' | System | 04 Sep 2020 17:17:55 |
| | System | 04 Sep 2020 17:17:55 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-04T13:17:41', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '0671671f-3582-40f6-9a46-4d014d1ed287' User entered 'No (N)' | System | 04 Sep 2020 17:17:55 |
| | System | 04 Sep 2020 17:17:55 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-04T13:17:45', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '0671671f-3582-40f6-9a46-4d014d1ed287' User entered 'None (1)' | System | 04 Sep 2020 17:17:55 |
| | System | 04 Sep 2020 17:17:55 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-04T13:17:52', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '0671671f-3582-40f6-9a46-4d014d1ed287' User entered '04 Sep 2020 13:17' | System | 04 Sep 2020 17:17:55 |
| | System | 04 Sep 2020 17:17:55 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '04 Sep 2020 12:00' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '05 Sep 2020 11:59' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 6' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-05T13:14:55', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '0022a4ba-b707-4811-8c82-12deae2ac649' | System | 05 Sep 2020 17:15:29 |
| User entered 'None (1)' | System | 05 Sep 2020 17:15:29 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:43

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-05T13:14:58', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '0022a4ba-b707-4811-8c82-12deae2ac649' User entered 'Yes (Y)' | System | 05 Sep 2020 17:15:29 |
| | System | 05 Sep 2020 17:15:29 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:43

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) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-05T13:15:10', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '0022a4ba-b707-4811-8c82-12deae2ac649' User entered '1' | System | 05 Sep 2020 17:15:29 |
| | System | 05 Sep 2020 17:15:29 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-05T13:15:13', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '0022a4ba-b707-4811-8c82-12deae2ac649' User entered 'No (N)' | System | 05 Sep 2020 17:15:29 |
| | System | 05 Sep 2020 17:15:29 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-05T13:15:16', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '0022a4ba-b707-4811-8c82-12deae2ac649' | System | 05 Sep 2020 17:15:29 |
| User entered 'None (1)' | System | 05 Sep 2020 17:15:29 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-05T13:15:27', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '0022a4ba-b707-4811-8c82-12deae2ac649' User entered '05 Sep 2020 13:15' | System | 05 Sep 2020 17:15:29 |
| | System | 05 Sep 2020 17:15:29 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '05 Sep 2020 12:00' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '06 Sep 2020 11:59' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 7' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-06T15:05:40', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '31c36d94-cede-4109-9168-671532a0c182' | System | 06 Sep 2020 19:06:06 |
| User entered 'None (1)' | System | 06 Sep 2020 19:06:06 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:43

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-06T15:05:45', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '31c36d94-cede-4109-9168-671532a0c182' User entered 'No (N)' | System | 06 Sep 2020 19:06:06 |
| | System | 06 Sep 2020 19:06:06 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-06T15:05:48', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '31c36d94-cede-4109-9168-671532a0c182' User entered 'No (N)' | System | 06 Sep 2020 19:06:06 |
| | System | 06 Sep 2020 19:06:06 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-06T15:05:58', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '31c36d94-cede-4109-9168-671532a0c182' | System | 06 Sep 2020 19:06:06 |
| User entered 'None (1)' | System | 06 Sep 2020 19:06:06 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-06T15:06:04', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '31c36d94-cede-4109-9168-671532a0c182' User entered '06 Sep 2020 15:06' | System | 06 Sep 2020 19:06:06 |
| | System | 06 Sep 2020 19:06:06 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '06 Sep 2020 12:00' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '07 Sep 2020 11:59' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-08-31T16:49:11', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'ff405e45-eee7-4671-81e0-a79b890fdaef' User entered 'None (0)' | System | 31 Aug 2020 20:51:32 |
| | System | 31 Aug 2020 20:51:32 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-08-31T16:49:13', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'ff405e45-eee7-4671-81e0-a79b890fdaef' User entered 'None (0)' | System | 31 Aug 2020 20:51:32 |
| | System | 31 Aug 2020 20:51:32 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-08-31T16:49:15', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'ff405e45-eee7-4671-81e0-a79b890fdaef' User entered 'None (0)' | System | 31 Aug 2020 20:51:32 |
| | System | 31 Aug 2020 20:51:32 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-08-31T16:49:17', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'ff405e45-eee7-4671-81e0-a79b890fdaef' User entered 'None (0)' | System | 31 Aug 2020 20:51:32 |
| | System | 31 Aug 2020 20:51:32 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-08-31T16:49:19', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'ff405e45-eee7-4671-81e0-a79b890fdaef' User entered 'None (0)' | System | 31 Aug 2020 20:51:32 |
| | System | 31 Aug 2020 20:51:32 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-08-31T16:49:21', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'ff405e45-eee7-4671-81e0-a79b890fdaef' User entered 'None (0)' | System | 31 Aug 2020 20:51:32 |
| | System | 31 Aug 2020 20:51:32 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-08-31T16:49:25', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'ff405e45-eee7-4671-81e0-a79b890fdaef' User entered 'No (N)' | System | 31 Aug 2020 20:51:32 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-08-31T16:49:33', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'ff405e45-eee7-4671-81e0-a79b890fdaef' User entered '31 Aug 2020 16:49' | System | 31 Aug 2020 20:51:32 |
| | System | 31 Aug 2020 20:51:32 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '31 Aug 2020 16:38' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '31 Aug 2020 19:08' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 1, after vaccination (at home)' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| | | |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| | | |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| | | |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| | | |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| | | |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| | | |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| | | |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| | | |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '31 Aug 2020 20:03' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '01 Sep 2020 11:59' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 2' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-01T18:51:07', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f93b0e9d-cf26-46cd-98f3-bcbbeae7cf3f' | System | 01 Sep 2020 22:51:14 |
| User entered 'No interference with activity (1)' | System | 01 Sep 2020 22:51:14 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-01T18:50:34', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f93b0e9d-cf26-46cd-98f3-bcbbeae7cf3f' User entered 'None (0)' | System | 01 Sep 2020 22:51:14 |
| | System | 01 Sep 2020 22:51:14 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-01T18:50:37', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f93b0e9d-cf26-46cd-98f3-bcbbeae7cf3f' User entered 'None (0)' | System | 01 Sep 2020 22:51:14 |
| | System | 01 Sep 2020 22:51:14 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-01T18:50:40', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f93b0e9d-cf26-46cd-98f3-bcbbeae7cf3f' User entered 'None (0)' | System | 01 Sep 2020 22:51:14 |
| | System | 01 Sep 2020 22:51:14 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-01T18:50:42', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f93b0e9d-cf26-46cd-98f3-bcbbeae7cf3f' User entered 'None (0)' | System | 01 Sep 2020 22:51:14 |
| | System | 01 Sep 2020 22:51:14 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

CHILLS

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-01T18:50:52', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f93b0e9d-cf26-46cd-98f3-bcbbeae7cf3f' User entered 'No interference with activity (1)' | System | 01 Sep 2020 22:51:14 |
| | System | 01 Sep 2020 22:51:14 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-01T18:50:56', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f93b0e9d-cf26-46cd-98f3-bcbbeae7cf3f' User entered 'No (N)' | System | 01 Sep 2020 22:51:14 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-01T18:51:13', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f93b0e9d-cf26-46cd-98f3-bcbbeae7cf3f' User entered '01 Sep 2020 18:51' | System | 01 Sep 2020 22:51:14 |
| | System | 01 Sep 2020 22:51:14 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '01 Sep 2020 12:00' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '02 Sep 2020 11:59' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 3' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-02T17:56:45', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '9117218f-dae3-45e3-9cf0-ea8dd8ba0c27' | System | 02 Sep 2020 21:57:21 |
| User entered 'No interference with activity (1)' | System | 02 Sep 2020 21:57:21 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-02T17:56:49', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '9117218f-dae3-45e3-9cf0-ea8dd8ba0c27' User entered 'None (0)' | System | 02 Sep 2020 21:57:21 |
| | System | 02 Sep 2020 21:57:21 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-02T17:56:51', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '9117218f-dae3-45e3-9cf0-ea8dd8ba0c27' User entered 'None (0)' | System | 02 Sep 2020 21:57:21 |
| | System | 02 Sep 2020 21:57:21 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-02T17:56:54', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '9117218f-dae3-45e3-9cf0-ea8dd8ba0c27' User entered 'None (0)' | System | 02 Sep 2020 21:57:21 |
| | System | 02 Sep 2020 21:57:21 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-02T17:56:56', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '9117218f-dae3-45e3-9cf0-ea8dd8ba0c27' User entered 'None (0)' | System | 02 Sep 2020 21:57:21 |
| | System | 02 Sep 2020 21:57:21 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-02T17:56:58', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '9117218f-dae3-45e3-9cf0-ea8dd8ba0c27' User entered 'None (0)' | System | 02 Sep 2020 21:57:21 |
| | System | 02 Sep 2020 21:57:21 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-02T17:57:01', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '9117218f-dae3-45e3-9cf0-ea8dd8ba0c27' | System | 02 Sep 2020 21:57:21 |
| User entered 'No (N)' | System | 02 Sep 2020 21:57:21 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-02T17:57:16', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '9117218f-dae3-45e3-9cf0-ea8dd8ba0c27' User entered '02 Sep 2020 17:57' | System | 02 Sep 2020 21:57:21 |
| | System | 02 Sep 2020 21:57:21 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '02 Sep 2020 12:00' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '03 Sep 2020 11:59' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 4' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-03T13:05:39', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '01a78a3a-6163-4497-9463-cf842fad01c5' User entered 'None (0)' | System | 03 Sep 2020 17:06:06 |
| | System | 03 Sep 2020 17:06:06 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-03T13:05:42', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '01a78a3a-6163-4497-9463-cf842fad01c5' User entered 'None (0)' | System | 03 Sep 2020 17:06:06 |
| | System | 03 Sep 2020 17:06:06 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-03T13:05:44', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '01a78a3a-6163-4497-9463-cf842fad01c5' User entered 'None (0)' | System | 03 Sep 2020 17:06:06 |
| | System | 03 Sep 2020 17:06:06 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-03T13:05:46', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '01a78a3a-6163-4497-9463-cf842fad01c5' User entered 'None (0)' | System | 03 Sep 2020 17:06:06 |
| | System | 03 Sep 2020 17:06:06 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-03T13:05:48', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '01a78a3a-6163-4497-9463-cf842fad01c5' User entered 'None (0)' | System | 03 Sep 2020 17:06:06 |
| | System | 03 Sep 2020 17:06:06 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-03T13:05:50', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '01a78a3a-6163-4497-9463-cf842fad01c5' User entered 'None (0)' | System | 03 Sep 2020 17:06:06 |
| | System | 03 Sep 2020 17:06:06 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-03T13:05:53', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '01a78a3a-6163-4497-9463-cf842fad01c5' User entered 'No (N)' | System | 03 Sep 2020 17:06:06 |
| | System | 03 Sep 2020 17:06:06 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-03T13:06:03', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '01a78a3a-6163-4497-9463-cf842fad01c5' User entered '03 Sep 2020 13:06' | System | 03 Sep 2020 17:06:06 |
| | System | 03 Sep 2020 17:06:06 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '03 Sep 2020 12:00' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '04 Sep 2020 11:59' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 5' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-04T13:17:57', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'b7e94f9e-9dc4-4ec1-815f-18628187bdd2' User entered 'None (0)' | System | 04 Sep 2020 17:18:28 |
| | System | 04 Sep 2020 17:18:28 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-04T13:18:01', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'b7e94f9e-9dc4-4ec1-815f-18628187bdd2' User entered 'None (0)' | System | 04 Sep 2020 17:18:28 |
| | System | 04 Sep 2020 17:18:28 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-04T13:18:02', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'b7e94f9e-9dc4-4ec1-815f-18628187bdd2' User entered 'None (0)' | System | 04 Sep 2020 17:18:28 |
| | System | 04 Sep 2020 17:18:28 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-04T13:18:05', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'b7e94f9e-9dc4-4ec1-815f-18628187bdd2' User entered 'None (0)' | System | 04 Sep 2020 17:18:28 |
| | System | 04 Sep 2020 17:18:28 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-04T13:18:06', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'b7e94f9e-9dc4-4ec1-815f-18628187bdd2' User entered 'None (0)' | System | 04 Sep 2020 17:18:28 |
| | System | 04 Sep 2020 17:18:28 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-04T13:18:16', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'b7e94f9e-9dc4-4ec1-815f-18628187bdd2' User entered 'None (0)' | System | 04 Sep 2020 17:18:28 |
| | System | 04 Sep 2020 17:18:28 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-04T13:18:19', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'b7e94f9e-9dc4-4ec1-815f-18628187bdd2' | System | 04 Sep 2020 17:18:28 |
| User entered 'No (N)' | System | 04 Sep 2020 17:18:28 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-04T13:18:26', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'b7e94f9e-9dc4-4ec1-815f-18628187bdd2' User entered '04 Sep 2020 13:18' | System | 04 Sep 2020 17:18:28 |
| | System | 04 Sep 2020 17:18:28 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '04 Sep 2020 12:00' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '05 Sep 2020 11:59' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 6' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-05T13:15:34', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'e7fe6e21-78f7-41ed-8549-87e817c18dbc' User entered 'None (0)' | System | 05 Sep 2020 17:15:59 |
| | System | 05 Sep 2020 17:15:59 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-05T13:15:36', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'e7fe6e21-78f7-41ed-8549-87e817c18dbc' User entered 'None (0)' | System | 05 Sep 2020 17:15:59 |
| | System | 05 Sep 2020 17:15:59 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-05T13:15:37', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'e7fe6e21-78f7-41ed-8549-87e817c18dbc' User entered 'None (0)' | System | 05 Sep 2020 17:15:59 |
| | System | 05 Sep 2020 17:15:59 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-05T13:15:39', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'e7fe6e21-78f7-41ed-8549-87e817c18dbc' User entered 'None (0)' | System | 05 Sep 2020 17:15:59 |
| | System | 05 Sep 2020 17:15:59 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-05T13:15:42', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'e7fe6e21-78f7-41ed-8549-87e817c18dbc' User entered 'None (0)' | System | 05 Sep 2020 17:15:59 |
| | System | 05 Sep 2020 17:15:59 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-05T13:15:45', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'e7fe6e21-78f7-41ed-8549-87e817c18dbc' User entered 'None (0)' | System | 05 Sep 2020 17:15:59 |
| | System | 05 Sep 2020 17:15:59 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-05T13:15:47', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'e7fe6e21-78f7-41ed-8549-87e817c18dbc' User entered 'No (N)' | System | 05 Sep 2020 17:15:59 |
| | System | 05 Sep 2020 17:15:59 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-05T13:15:56', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'e7fe6e21-78f7-41ed-8549-87e817c18dbc' User entered '05 Sep 2020 13:15' | System | 05 Sep 2020 17:15:59 |
| | System | 05 Sep 2020 17:15:59 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '05 Sep 2020 12:00' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '06 Sep 2020 11:59' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 7' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-06T15:06:08', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '608e03c4-1faf-4052-a1bd-71af16082f78' User entered 'None (0)' | System | 06 Sep 2020 19:06:32 |
| | System | 06 Sep 2020 19:06:32 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-06T15:06:10', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '608e03c4-1faf-4052-a1bd-71af16082f78' User entered 'None (0)' | System | 06 Sep 2020 19:06:32 |
| | System | 06 Sep 2020 19:06:32 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-06T15:06:12', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '608e03c4-1faf-4052-a1bd-71af16082f78' User entered 'None (0)' | System | 06 Sep 2020 19:06:32 |
| | System | 06 Sep 2020 19:06:32 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-06T15:06:14', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '608e03c4-1faf-4052-a1bd-71af16082f78' User entered 'None (0)' | System | 06 Sep 2020 19:06:32 |
| | System | 06 Sep 2020 19:06:32 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-06T15:06:16', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '608e03c4-1faf-4052-a1bd-71af16082f78' User entered 'None (0)' | System | 06 Sep 2020 19:06:32 |
| | System | 06 Sep 2020 19:06:32 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-06T15:06:18', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '608e03c4-1faf-4052-a1bd-71af16082f78' User entered 'None (0)' | System | 06 Sep 2020 19:06:32 |
| | System | 06 Sep 2020 19:06:32 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-06T15:06:21', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '608e03c4-1faf-4052-a1bd-71af16082f78' User entered 'No (N)' | System | 06 Sep 2020 19:06:32 |
| | System | 06 Sep 2020 19:06:32 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-06T15:06:30', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '608e03c4-1faf-4052-a1bd-71af16082f78' User entered '06 Sep 2020 15:06' | System | 06 Sep 2020 19:06:32 |
| | System | 06 Sep 2020 19:06:32 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '06 Sep 2020 12:00' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '07 Sep 2020 11:59' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | James Lovette (b) (4) | 22 Sep 2020 20:05:01 |

US3762120

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '07 Sep 2020' | James Lovette (b) (4) | 22 Sep 2020 20:05:01 |

US3762120

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Contact Made (CONTACT MADE)' | James Lovette (b) (4) | 22 Sep 2020 20:05:01 |

US3762120

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | James Lovette (b) (4) | 22 Sep 2020 20:05:01 |

US3762120

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | James Lovette (b) (4) | 22 Sep 2020 20:05:08 |

US3762120

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'I' | System | 22 Sep 2020 20:05:08 |

US3762120

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | James Lovette (b) (4) | 22 Sep 2020 20:06:58 |

US3762120

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '14 Sep 2020' | James Lovette (b) (4) | 22 Sep 2020 20:06:58 |

US3762120

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Contact Made (CONTACT MADE)' | James Lovette (b) (4) | 22 Sep 2020 20:06:58 |

US3762120

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | James Lovette (b) (4) | 22 Sep 2020 20:06:58 |

US3762120

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | James Lovette (b) (4) | 22 Sep 2020 20:07:04 |

US3762120

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'I' | System | 22 Sep 2020 20:07:04 |

US3762120

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | James Lovette (b) (4) | 22 Sep 2020 20:08:14 |

US3762120

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '21 Sep 2020' | James Lovette (b) (4) | 22 Sep 2020 20:08:14 |

US3762120

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Contact Made (CONTACT MADE)' | James Lovette (b) (4) | 22 Sep 2020 20:08:14 |

US3762120

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | James Lovette (b) (4) | 22 Sep 2020 20:08:14 |

US3762120

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | James Lovette (b) (4) | 22 Sep 2020 20:08:20 |

US3762120

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'I' | System | 22 Sep 2020 20:08:20 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:43

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | Samantha Wheeler (b) (4) | 28 Sep 2020 18:56:20 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '28 Sep 2020' | (b) (4) Samantha Wheeler (b) (4) | 28 Sep 2020 18:56:20 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:43

[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 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Clinic (Clinic)' | (b) (4) Samantha Wheeler (b) (4) (b) (4) | 28 Sep 2020 18:56:20 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:43

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'VISIT2' | System | 28 Sep 2020 18:56:20 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User accepted default value 'Pre-Dose (PREDOSE)' | James Lovette (b) (4) (b) (4) | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | James Lovette (b) (4) | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '28 Sep 2020' | James Lovette (b) (4) | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '14:02' | James Lovette (b) (4) | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered '28 Sep 2020 14:02' | System | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '97.9' F | James Lovette (b) (4) | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Oral (Oral)' | James Lovette (b) (4) | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | James Lovette (b) (4) | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '61' | James Lovette (b) (4) | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'bpm' | System | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '16' | James Lovette (b) (4) | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'breaths/min' | System | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '111' | James Lovette (b) (4) | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'mmHg' | System | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User closed query 'Per CDM: Response noted. However, please indicate if CS/NCS and report as AE, if appropriate' (Site from DM). | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 19:04:46 |
| Query 'Per CDM: Response noted. However, please indicate if CS/NCS and report as AE, if appropriate' answered with 'NCS- normal per patient' (Site from DM). | Samantha Wheeler (b) (4) (b) (4) | 06 Oct 2020 19:25:41 |
| User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | (b) (4), (b) (6) | 01 Oct 2020 17:24:03 |
| User opened query 'Per CDM: Response noted. However, please indicate if CS/NCS and report as AE, if appropriate' (Site from DM). | (b) (4), (b) (6) | 01 Oct 2020 17:24:01 |
| Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'correct per source' (Site from System). | James Lovette (b) (4) (b) (4) | 30 Sep 2020 18:13:27 |
| User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | | 30 Sep 2020 18:12:57 |
| User entered '48' | James Lovette (b) (4) (b) (4) | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:43

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'mmHg' | System | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User accepted default value 'Post-Dose (POSTDOSE)' | James Lovette (b) (4) (b) (4) | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | James Lovette (b) (4) | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '28 Sep 2020' | James Lovette (b) (4) | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '15:13' | James Lovette (b) (4) | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered '28 Sep 2020 15:13' | System | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '97.8' F | James Lovette (b) (4) | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Oral (Oral)' | James Lovette (b) (4) | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | James Lovette (b) (4) | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '52' | James Lovette (b) (4) | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'bpm' | System | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '14' | James Lovette (b) (4) | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'breaths/min' | System | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '118' | James Lovette (b) (4) | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'mmHg' | System | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '73' | James Lovette (b) (4) | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:43

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'mmHg' | System | 30 Sep 2020 18:12:57 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:43

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | James Lovette (b) (4) | 30 Sep 2020 18:13:40 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:43

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '28 Sep 2020' | James Lovette (b) (4) | 30 Sep 2020 18:13:40 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:43

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | Samantha Wheeler (b) (4) | 28 Sep 2020 18:56:49 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:43

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | Samantha Wheeler (b) (4) | 28 Sep 2020 18:56:49 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:43

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 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | Samantha Wheeler (b) (4) | 28 Sep 2020 18:56:49 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:43

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:43

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '28 Sep 2020' | (b) (4) Samantha Wheeler (b) (4) (b) (4) | 28 Sep 2020 18:56:49 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:43

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '14:43' | (b) (4) Samantha Wheeler (b) (4) | 28 Sep 2020 18:56:49 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:43

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered '28 Sep 2020 14:43' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:43

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Left Arm (LEFT ARM)' | Samantha Wheeler (b) (4) | 28 Sep 2020 18:56:49 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:43

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'ONCE' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:43

[What was the route of administration for the study treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'INTRAMUSCULAR' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:43

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | James Lovette (b) (4) | 30 Sep 2020 18:13:59 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:43

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '28 Sep 2020' | James Lovette (b) (4) | 30 Sep 2020 18:13:59 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:43

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '14:09' | James Lovette (b) (4) | 30 Sep 2020 18:13:59 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:43

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered '28 Sep 2020 14:09' | System | 30 Sep 2020 18:13:59 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:41:43

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '28 Sep 2020' | James Lovette (b) (4) | 30 Sep 2020 18:14:40 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:41:43

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | James Lovette (b) (4) (b) (4) | 30 Sep 2020 18:14:40 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:41:43

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | James Lovette (b) (4) | 30 Sep 2020 18:14:40 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:41:43

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '14:11' | James Lovette (b) (4) | 30 Sep 2020 18:14:40 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:41:43

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered '28 Sep 2020 14:11' | System | 30 Sep 2020 18:14:40 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:41:43

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | James Lovette (b) (4) (b) (4) | 30 Sep 2020 18:14:40 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:41:43

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | James Lovette (b) (4) | 30 Sep 2020 18:14:40 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:41:43

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | James Lovette (b) (4) | 30 Sep 2020 18:14:40 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:41:43

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered empty. | System | 30 Sep 2020 18:14:40 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | James Lovette (b) (4) | 30 Sep 2020 18:14:48 |

US3762120

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'I' | System | 30 Sep 2020 18:14:48 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 28 Sep 2020 18:56:49 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T15:15:14', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '67034b47-e9a2-44c0-b8f1-47bbe0d3758b' User entered 'Yes (Y)' | System | 28 Sep 2020 19:15:38 |
| | System | 28 Sep 2020 19:15:38 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T15:15:24', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '67034b47-e9a2-44c0-b8f1-47bbe0d3758b' User entered '97.8' | System | 28 Sep 2020 19:15:38 |
| | System | 28 Sep 2020 19:15:38 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T15:15:27', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '67034b47-e9a2-44c0-b8f1-47bbe0d3758b' User entered 'No (N)' | System | 28 Sep 2020 19:15:38 |
| | System | 28 Sep 2020 19:15:38 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T15:15:33', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '67034b47-e9a2-44c0-b8f1-47bbe0d3758b' User entered '28 Sep 2020 15:15' | System | 28 Sep 2020 19:15:38 |
| | System | 28 Sep 2020 19:15:38 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '28 Sep 2020 15:03' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '28 Sep 2020 17:33' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 28 Sep 2020 18:56:49 |
| User entered 'Day 1, after vaccination (at home)' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T20:33:27', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f4fae52f-216f-4a0e-a530-e78ccf3d9974' User entered 'Yes (Y)' | System | 29 Sep 2020 00:33:53 |
| | System | 29 Sep 2020 00:33:53 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T20:33:39', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f4fae52f-216f-4a0e-a530-e78ccf3d9974' User entered '98.0' | System | 29 Sep 2020 00:33:53 |
| | System | 29 Sep 2020 00:33:53 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T20:33:42', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f4fae52f-216f-4a0e-a530-e78ccf3d9974' | System | 29 Sep 2020 00:33:53 |
| User entered 'No (N)' | System | 29 Sep 2020 00:33:53 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T20:33:50', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f4fae52f-216f-4a0e-a530-e78ccf3d9974' User entered '28 Sep 2020 20:33' | System | 29 Sep 2020 00:33:53 |
| | System | 29 Sep 2020 00:33:53 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '28 Sep 2020 18:28' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '29 Sep 2020 11:59' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 28 Sep 2020 18:56:49 |
| User entered 'Day 2' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:43

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-29T19:35:12', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'be59e51c-f42d-4d36-a652-78ae90ac8fd6' User entered 'Yes (Y)' | System | 29 Sep 2020 23:35:34 |
| | System | 29 Sep 2020 23:35:34 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:43

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-29T19:35:20', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'be59e51c-f42d-4d36-a652-78ae90ac8fd6' User entered '99.8' | System | 29 Sep 2020 23:35:34 |
| | System | 29 Sep 2020 23:35:34 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-29T19:35:23', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'be59e51c-f42d-4d36-a652-78ae90ac8fd6' | System | 29 Sep 2020 23:35:34 |
| User entered 'No (N)' | System | 29 Sep 2020 23:35:34 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-29T19:35:30', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'be59e51c-f42d-4d36-a652-78ae90ac8fd6' User entered '29 Sep 2020 19:35' | System | 29 Sep 2020 23:35:34 |
| | System | 29 Sep 2020 23:35:34 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '29 Sep 2020 12:00' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '30 Sep 2020 11:59' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 28 Sep 2020 18:56:49 |
| User entered 'Day 3' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:43

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-30T17:59:52', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'cbb84466-612e-41a8-aa62-7f0f0d16bd3a' User entered 'Yes (Y)' | System | 30 Sep 2020 22:00:25 |
| | System | 30 Sep 2020 22:00:25 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:43

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-30T18:00:11', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'cbb84466-612e-41a8-aa62-7f0f0d16bd3a' User entered '100.4' | System | 30 Sep 2020 22:00:25 |
| | System | 30 Sep 2020 22:00:25 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-30T18:00:14', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'cbb84466-612e-41a8-aa62-7f0f0d16bd3a' User entered 'No (N)' | System | 30 Sep 2020 22:00:25 |
| | System | 30 Sep 2020 22:00:25 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-30T18:00:22', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'cbb84466-612e-41a8-aa62-7f0f0d16bd3a' User entered '30 Sep 2020 18:00' | System | 30 Sep 2020 22:00:25 |
| | System | 30 Sep 2020 22:00:25 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '30 Sep 2020 12:00' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '01 Oct 2020 11:59' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 28 Sep 2020 18:56:49 |
| User entered 'Day 4' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:43

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-01T17:04:43', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '9a12be59-2512-4ea7-b896-88604235a1d1' User entered 'Yes (Y)' | System | 01 Oct 2020 21:05:18 |
| | System | 01 Oct 2020 21:05:18 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:43

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-01T17:05:04', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '9a12be59-2512-4ea7-b896-88604235a1d1' User entered '98.4' | System | 01 Oct 2020 21:05:18 |
| | System | 01 Oct 2020 21:05:18 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-01T17:05:05', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '9a12be59-2512-4ea7-b896-88604235a1d1' User entered 'No (N)' | System | 01 Oct 2020 21:05:18 |
| | System | 01 Oct 2020 21:05:18 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-01T17:05:15', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '9a12be59-2512-4ea7-b896-88604235a1d1' User entered '01 Oct 2020 17:05' | System | 01 Oct 2020 21:05:18 |
| | System | 01 Oct 2020 21:05:18 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '01 Oct 2020 12:00' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '02 Oct 2020 11:59' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 28 Sep 2020 18:56:49 |
| User entered 'Day 5' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:43

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-02T16:45:20', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'e4374097-deca-41f4-b88b-c89b6e83b2a2' User entered 'Yes (Y)' | System | 02 Oct 2020 20:45:39 |
| | System | 02 Oct 2020 20:45:39 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:43

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-02T16:45:28', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'e4374097-deca-41f4-b88b-c89b6e83b2a2' User entered '97.7' | System | 02 Oct 2020 20:45:39 |
| | System | 02 Oct 2020 20:45:39 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-02T16:45:31', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'e4374097-deca-41f4-b88b-c89b6e83b2a2' | System | 02 Oct 2020 20:45:39 |
| User entered 'No (N)' | System | 02 Oct 2020 20:45:39 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-02T16:45:36', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'e4374097-deca-41f4-b88b-c89b6e83b2a2' User entered '02 Oct 2020 16:45' | System | 02 Oct 2020 20:45:39 |
| | System | 02 Oct 2020 20:45:39 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '02 Oct 2020 12:00' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '03 Oct 2020 11:59' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 28 Sep 2020 18:56:49 |
| User entered 'Day 6' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:43

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T07:49:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '4ce7a00d-3501-4ca8-9f0d-c8d15532a3d9' User entered 'Yes (Y)' | System | 04 Oct 2020 11:49:16 |
| | System | 04 Oct 2020 11:49:16 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:43

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T07:49:06', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '4ce7a00d-3501-4ca8-9f0d-c8d15532a3d9' User entered '97.4' | System | 04 Oct 2020 11:49:16 |
| | System | 04 Oct 2020 11:49:16 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T07:49:10', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '4ce7a00d-3501-4ca8-9f0d-c8d15532a3d9' | System | 04 Oct 2020 11:49:16 |
| User entered 'No (N)' | System | 04 Oct 2020 11:49:16 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T07:49:14', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '4ce7a00d-3501-4ca8-9f0d-c8d15532a3d9' User entered '04 Oct 2020 07:49' | System | 04 Oct 2020 11:49:16 |
| | System | 04 Oct 2020 11:49:16 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '03 Oct 2020 12:00' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '04 Oct 2020 11:59' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 28 Sep 2020 18:56:49 |
| User entered 'Day 7' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:43

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T16:00:34', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '4df77c45-aaf8-44a6-b7b9-fb13512eb714' User entered 'Yes (Y)' | System | 04 Oct 2020 20:00:53 |
| | System | 04 Oct 2020 20:00:53 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:43

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T16:00:44', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '4df77c45-aaf8-44a6-b7b9-fb13512eb714' User entered '97.8' | System | 04 Oct 2020 20:00:53 |
| | System | 04 Oct 2020 20:00:53 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T16:00:47', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '4df77c45-aaf8-44a6-b7b9-fb13512eb714' | System | 04 Oct 2020 20:00:53 |
| User entered 'No (N)' | System | 04 Oct 2020 20:00:53 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T16:00:51', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '4df77c45-aaf8-44a6-b7b9-fb13512eb714' User entered '04 Oct 2020 16:00' | System | 04 Oct 2020 20:00:53 |
| | System | 04 Oct 2020 20:00:53 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '04 Oct 2020 12:00' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '05 Oct 2020 11:59' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 28 Sep 2020 18:56:49 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T15:15:44', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '7faabf4e-e17e-49f9-a749-787c3b4cbc9a' | System | 28 Sep 2020 19:16:09 |
| User entered 'None (1)' | System | 28 Sep 2020 19:16:09 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T15:15:54', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '7faabf4e-e17e-49f9-a749-787c3b4cbc9a' User entered 'No (N)' | System | 28 Sep 2020 19:16:09 |
| | System | 28 Sep 2020 19:16:09 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T15:15:57', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '7faabf4e-e17e-49f9-a749-787c3b4cbc9a' User entered 'No (N)' | System | 28 Sep 2020 19:16:09 |
| | System | 28 Sep 2020 19:16:09 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T15:16:01', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '7faabf4e-e17e-49f9-a749-787c3b4cbc9a' | System | 28 Sep 2020 19:16:09 |
| User entered 'None (1)' | System | 28 Sep 2020 19:16:09 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T15:16:07', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '7faabf4e-e17e-49f9-a749-787c3b4cbc9a' User entered '28 Sep 2020 15:16' | System | 28 Sep 2020 19:16:09 |
| | System | 28 Sep 2020 19:16:09 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '28 Sep 2020 15:03' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '28 Sep 2020 17:33' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 28 Sep 2020 18:56:49 |
| User entered 'Day 1, after vaccination (at home)' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T20:33:59', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'ea99c78e-8527-4c93-90c6-40203aea69d8' | System | 29 Sep 2020 00:34:44 |
| User entered 'Does not interfere with activity (2)' | System | 29 Sep 2020 00:34:44 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T20:34:03', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'ea99c78e-8527-4c93-90c6-40203aea69d8' User entered 'No (N)' | System | 29 Sep 2020 00:34:44 |
| | System | 29 Sep 2020 00:34:44 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T20:34:21', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'ea99c78e-8527-4c93-90c6-40203aea69d8' User entered 'No (N)' | System | 29 Sep 2020 00:34:44 |
| | System | 29 Sep 2020 00:34:44 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T20:34:34', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'ea99c78e-8527-4c93-90c6-40203aea69d8' User entered 'None (1)' | System | 29 Sep 2020 00:34:44 |
| | System | 29 Sep 2020 00:34:44 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T20:34:42', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'ea99c78e-8527-4c93-90c6-40203aea69d8' User entered '28 Sep 2020 20:34' | System | 29 Sep 2020 00:34:44 |
| | System | 29 Sep 2020 00:34:44 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '28 Sep 2020 18:28' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '29 Sep 2020 11:59' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 28 Sep 2020 18:56:49 |
| User entered 'Day 2' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-29T19:35:41', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '678843d2-eb5f-4c3e-9890-32325c5a76d8' | System | 29 Sep 2020 23:37:23 |
| User entered 'Does not interfere with activity (2)' | System | 29 Sep 2020 23:37:23 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:43

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-29T19:35:44', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '678843d2-eb5f-4c3e-9890-32325c5a76d8' User entered 'No (N)' | System | 29 Sep 2020 23:37:23 |
| | System | 29 Sep 2020 23:37:23 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-29T19:35:50', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '678843d2-eb5f-4c3e-9890-32325c5a76d8' User entered 'Yes (Y)' | System | 29 Sep 2020 23:37:23 |
| | System | 29 Sep 2020 23:37:23 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:43

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) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-29T19:37:02', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '678843d2-eb5f-4c3e-9890-32325c5a76d8' User entered '70' | System | 29 Sep 2020 23:37:23 |
| | System | 29 Sep 2020 23:37:23 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-29T19:37:11', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '678843d2-eb5f-4c3e-9890-32325c5a76d8' User entered 'None (1)' | System | 29 Sep 2020 23:37:23 |
| | System | 29 Sep 2020 23:37:23 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-29T19:37:22', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '678843d2-eb5f-4c3e-9890-32325c5a76d8' User entered '29 Sep 2020 19:37' | System | 29 Sep 2020 23:37:23 |
| | System | 29 Sep 2020 23:37:23 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '29 Sep 2020 12:00' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '30 Sep 2020 11:59' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 28 Sep 2020 18:56:49 |
| User entered 'Day 3' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-30T18:00:27', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '470fe6ff-08d1-456a-9f4c-5a73fe8b3269' | System | 30 Sep 2020 22:01:37 |
| User entered 'Does not interfere with activity (2)' | System | 30 Sep 2020 22:01:37 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:43

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-30T18:00:30', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '470fe6ff-08d1-456a-9f4c-5a73fe8b3269' | System | 30 Sep 2020 22:01:37 |
| User entered 'Yes (Y)' | System | 30 Sep 2020 22:01:37 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:43

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) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-30T18:00:41', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '470fe6ff-08d1-456a-9f4c-5a73fe8b3269' User entered '83' | System | 30 Sep 2020 22:01:37 |
| | System | 30 Sep 2020 22:01:37 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-30T18:00:46', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '470fe6ff-08d1-456a-9f4c-5a73fe8b3269' User entered 'Yes (Y)' | System | 30 Sep 2020 22:01:37 |
| | System | 30 Sep 2020 22:01:37 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:43

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) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-30T18:00:56', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '470fe6ff-08d1-456a-9f4c-5a73fe8b3269' User entered '83' | System | 30 Sep 2020 22:01:37 |
| | System | 30 Sep 2020 22:01:37 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-30T18:01:19', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '470fe6ff-08d1-456a-9f4c-5a73fe8b3269' | System | 30 Sep 2020 22:01:37 |
| User entered 'Does not interfere with activity (2)' | System | 30 Sep 2020 22:01:37 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-30T18:01:31', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '470fe6ff-08d1-456a-9f4c-5a73fe8b3269' User entered '30 Sep 2020 18:01' | System | 30 Sep 2020 22:01:37 |
| | System | 30 Sep 2020 22:01:37 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '30 Sep 2020 12:00' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '01 Oct 2020 11:59' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 28 Sep 2020 18:56:49 |
| User entered 'Day 4' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-01T17:05:24', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'c58f1cdc-2a9e-40ef-bbb7-89868d53f553' | System | 01 Oct 2020 21:06:19 |
| User entered 'Does not interfere with activity (2)' | System | 01 Oct 2020 21:06:19 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:43

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-01T17:05:31', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'c58f1cdc-2a9e-40ef-bbb7-89868d53f553' | System | 01 Oct 2020 21:06:19 |
| User entered 'Yes (Y)' | System | 01 Oct 2020 21:06:19 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:43

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) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-01T17:05:47', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'c58f1cdc-2a9e-40ef-bbb7-89868d53f553' User entered '70' | System | 01 Oct 2020 21:06:19 |
| | System | 01 Oct 2020 21:06:19 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-01T17:05:50', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'c58f1cdc-2a9e-40ef-bbb7-89868d53f553' | System | 01 Oct 2020 21:06:19 |
| User entered 'Yes (Y)' | System | 01 Oct 2020 21:06:19 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:43

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) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-01T17:05:58', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'c58f1cdc-2a9e-40ef-bbb7-89868d53f553' | System | 01 Oct 2020 21:06:19 |
| User entered '80' | System | 01 Oct 2020 21:06:19 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-01T17:06:05', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'c58f1cdc-2a9e-40ef-bbb7-89868d53f553' | System | 01 Oct 2020 21:06:19 |
| User entered 'Does not interfere with activity (2)' | System | 01 Oct 2020 21:06:19 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-01T17:06:17', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'c58f1cdc-2a9e-40ef-bbb7-89868d53f553' User entered '01 Oct 2020 17:06' | System | 01 Oct 2020 21:06:19 |
| | System | 01 Oct 2020 21:06:19 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '01 Oct 2020 12:00' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '02 Oct 2020 11:59' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 28 Sep 2020 18:56:49 |
| User entered 'Day 5' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-02T16:45:44', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '781a2e9e-6f7b-462b-8afe-ee5512799084' User entered 'None (1)' | System | 02 Oct 2020 20:46:35 |
| | System | 02 Oct 2020 20:46:35 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:43

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-02T16:45:48', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '781a2e9e-6f7b-462b-8afe-ee5512799084' User entered 'No (N)' | System | 02 Oct 2020 20:46:35 |
| | System | 02 Oct 2020 20:46:35 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-02T16:45:52', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '781a2e9e-6f7b-462b-8afe-ee5512799084' User entered 'Yes (Y)' | System | 02 Oct 2020 20:46:35 |
| | System | 02 Oct 2020 20:46:35 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:43

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) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-02T16:46:14', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '781a2e9e-6f7b-462b-8afe-ee5512799084' User entered '50' | System | 02 Oct 2020 20:46:35 |
| | System | 02 Oct 2020 20:46:35 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-02T16:46:18', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '781a2e9e-6f7b-462b-8afe-ee5512799084' | System | 02 Oct 2020 20:46:35 |
| User entered 'None (1)' | System | 02 Oct 2020 20:46:35 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-02T16:46:31', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '781a2e9e-6f7b-462b-8afe-ee5512799084' User entered '02 Oct 2020 16:46' | System | 02 Oct 2020 20:46:35 |
| | System | 02 Oct 2020 20:46:35 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '02 Oct 2020 12:00' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '03 Oct 2020 11:59' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 28 Sep 2020 18:56:49 |
| User entered 'Day 6' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T07:49:18', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'c42dd2f8-014a-433c-9020-d6bea788f367' | System | 04 Oct 2020 11:49:47 |
| User entered 'None (1)' | System | 04 Oct 2020 11:49:47 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:43

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T07:49:22', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'c42dd2f8-014a-433c-9020-d6bea788f367' User entered 'No (N)' | System | 04 Oct 2020 11:49:47 |
| | System | 04 Oct 2020 11:49:47 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T07:49:30', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'c42dd2f8-014a-433c-9020-d6bea788f367' User entered 'Yes (Y)' | System | 04 Oct 2020 11:49:47 |
| | System | 04 Oct 2020 11:49:47 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:43

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) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T07:49:35', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'c42dd2f8-014a-433c-9020-d6bea788f367' User entered '20' | System | 04 Oct 2020 11:49:47 |
| | System | 04 Oct 2020 11:49:47 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T07:49:38', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'c42dd2f8-014a-433c-9020-d6bea788f367' | System | 04 Oct 2020 11:49:47 |
| User entered 'None (1)' | System | 04 Oct 2020 11:49:47 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T07:49:44', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'c42dd2f8-014a-433c-9020-d6bea788f367' User entered '04 Oct 2020 07:49' | System | 04 Oct 2020 11:49:47 |
| | System | 04 Oct 2020 11:49:47 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '03 Oct 2020 12:00' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '04 Oct 2020 11:59' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 28 Sep 2020 18:56:49 |
| User entered 'Day 7' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T16:00:55', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '98c7af3c-45c5-4db0-9b90-d800189b8c68' User entered 'None (1)' | System | 04 Oct 2020 20:01:33 |
| | System | 04 Oct 2020 20:01:33 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:43

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T16:00:59', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '98c7af3c-45c5-4db0-9b90-d800189b8c68' User entered 'No (N)' | System | 04 Oct 2020 20:01:33 |
| | System | 04 Oct 2020 20:01:33 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T16:01:04', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '98c7af3c-45c5-4db0-9b90-d800189b8c68' User entered 'Yes (Y)' | System | 04 Oct 2020 20:01:33 |
| | System | 04 Oct 2020 20:01:33 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:43

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) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T16:01:17', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '98c7af3c-45c5-4db0-9b90-d800189b8c68' User entered '30' | System | 04 Oct 2020 20:01:33 |
| | System | 04 Oct 2020 20:01:33 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:43

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T16:01:22', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '98c7af3c-45c5-4db0-9b90-d800189b8c68' User entered 'None (1)' | System | 04 Oct 2020 20:01:33 |
| | System | 04 Oct 2020 20:01:33 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:43

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T16:01:30', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '98c7af3c-45c5-4db0-9b90-d800189b8c68' User entered '04 Oct 2020 16:01' | System | 04 Oct 2020 20:01:33 |
| | System | 04 Oct 2020 20:01:33 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '04 Oct 2020 12:00' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '05 Oct 2020 11:59' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 28 Sep 2020 18:56:49 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T15:16:14', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '0f5cc9e0-f26b-48f7-8988-10c531da7d4f' User entered 'None (0)' | System | 28 Sep 2020 19:16:43 |
| | System | 28 Sep 2020 19:16:43 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T15:16:16', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '0f5cc9e0-f26b-48f7-8988-10c531da7d4f' User entered 'None (0)' | System | 28 Sep 2020 19:16:43 |
| | System | 28 Sep 2020 19:16:43 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T15:16:18', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '0f5cc9e0-f26b-48f7-8988-10c531da7d4f' User entered 'None (0)' | System | 28 Sep 2020 19:16:43 |
| | System | 28 Sep 2020 19:16:43 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T15:16:20', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '0f5cc9e0-f26b-48f7-8988-10c531da7d4f' User entered 'None (0)' | System | 28 Sep 2020 19:16:43 |
| | System | 28 Sep 2020 19:16:43 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T15:16:23', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '0f5cc9e0-f26b-48f7-8988-10c531da7d4f' User entered 'None (0)' | System | 28 Sep 2020 19:16:43 |
| | System | 28 Sep 2020 19:16:43 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T15:16:28', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '0f5cc9e0-f26b-48f7-8988-10c531da7d4f' User entered 'None (0)' | System | 28 Sep 2020 19:16:43 |
| | System | 28 Sep 2020 19:16:43 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T15:16:35', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '0f5cc9e0-f26b-48f7-8988-10c531da7d4f' User entered 'No (N)' | System | 28 Sep 2020 19:16:43 |
| | System | 28 Sep 2020 19:16:43 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T15:16:41', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '0f5cc9e0-f26b-48f7-8988-10c531da7d4f' User entered '28 Sep 2020 15:16' | System | 28 Sep 2020 19:16:43 |
| | System | 28 Sep 2020 19:16:43 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '28 Sep 2020 15:03' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '28 Sep 2020 17:33' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 28 Sep 2020 18:56:49 |
| User entered 'Day 1, after vaccination (at home)' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T20:34:47', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '4715ba52-a83a-498b-8e28-ac77b1a9d065' User entered 'None (0)' | System | 29 Sep 2020 00:35:15 |
| | System | 29 Sep 2020 00:35:15 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T20:34:49', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '4715ba52-a83a-498b-8e28-ac77b1a9d065' User entered 'None (0)' | System | 29 Sep 2020 00:35:15 |
| | System | 29 Sep 2020 00:35:15 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T20:34:52', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '4715ba52-a83a-498b-8e28-ac77b1a9d065' User entered 'None (0)' | System | 29 Sep 2020 00:35:15 |
| | System | 29 Sep 2020 00:35:15 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T20:34:54', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '4715ba52-a83a-498b-8e28-ac77b1a9d065' User entered 'None (0)' | System | 29 Sep 2020 00:35:15 |
| | System | 29 Sep 2020 00:35:15 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T20:34:57', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '4715ba52-a83a-498b-8e28-ac77b1a9d065' User entered 'None (0)' | System | 29 Sep 2020 00:35:15 |
| | System | 29 Sep 2020 00:35:15 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T20:35:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '4715ba52-a83a-498b-8e28-ac77b1a9d065' User entered 'None (0)' | System | 29 Sep 2020 00:35:15 |
| | System | 29 Sep 2020 00:35:15 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T20:35:03', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '4715ba52-a83a-498b-8e28-ac77b1a9d065' User entered 'No (N)' | System | 29 Sep 2020 00:35:15 |
| | System | 29 Sep 2020 00:35:15 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-28T20:35:12', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '4715ba52-a83a-498b-8e28-ac77b1a9d065' User entered '28 Sep 2020 20:35' | System | 29 Sep 2020 00:35:15 |
| | System | 29 Sep 2020 00:35:15 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '28 Sep 2020 18:28' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '29 Sep 2020 11:59' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 28 Sep 2020 18:56:49 |
| User entered 'Day 2' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-29T19:37:37', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'c102ec32-e49c-4fec-98b8-d7c942f37d6c' | System | 29 Sep 2020 23:38:26 |
| User entered 'No interference with activity (1)' | System | 29 Sep 2020 23:38:26 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-29T19:37:45', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'c102ec32-e49c-4fec-98b8-d7c942f37d6c' | System | 29 Sep 2020 23:38:26 |
| User entered 'No interference with activity (1)' | System | 29 Sep 2020 23:38:26 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-29T19:37:50', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'c102ec32-e49c-4fec-98b8-d7c942f37d6c' | System | 29 Sep 2020 23:38:26 |
| User entered 'No interference with activity (1)' | System | 29 Sep 2020 23:38:26 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-29T19:37:57', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'c102ec32-e49c-4fec-98b8-d7c942f37d6c' | System | 29 Sep 2020 23:38:26 |
| User entered 'No interference with activity (1)' | System | 29 Sep 2020 23:38:26 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-29T19:38:02', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'c102ec32-e49c-4fec-98b8-d7c942f37d6c' User entered 'None (0)' | System | 29 Sep 2020 23:38:26 |
| | System | 29 Sep 2020 23:38:26 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-29T19:38:06', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'c102ec32-e49c-4fec-98b8-d7c942f37d6c' | System | 29 Sep 2020 23:38:26 |
| User entered 'No interference with activity (1)' | System | 29 Sep 2020 23:38:26 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-29T19:38:09', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'c102ec32-e49c-4fec-98b8-d7c942f37d6c' User entered 'No (N)' | System | 29 Sep 2020 23:38:26 |
| | System | 29 Sep 2020 23:38:26 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-29T19:38:24', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'c102ec32-e49c-4fec-98b8-d7c942f37d6c' User entered '29 Sep 2020 19:38' | System | 29 Sep 2020 23:38:26 |
| | System | 29 Sep 2020 23:38:26 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '29 Sep 2020 12:00' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '30 Sep 2020 11:59' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 28 Sep 2020 18:56:49 |
| User entered 'Day 3' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-30T18:01:35', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '40c0b578-ad60-4a81-b7e3-d899be8ceed3' User entered 'None (0)' | System | 30 Sep 2020 22:02:23 |
| | System | 30 Sep 2020 22:02:23 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-30T18:02:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '40c0b578-ad60-4a81-b7e3-d899be8ceed3' | System | 30 Sep 2020 22:02:23 |
| User entered 'No interference with activity (1)' | System | 30 Sep 2020 22:02:23 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-30T18:01:41', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '40c0b578-ad60-4a81-b7e3-d899be8ceed3' User entered 'None (0)' | System | 30 Sep 2020 22:02:23 |
| | System | 30 Sep 2020 22:02:23 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-30T18:01:43', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '40c0b578-ad60-4a81-b7e3-d899be8ceed3' User entered 'None (0)' | System | 30 Sep 2020 22:02:23 |
| | System | 30 Sep 2020 22:02:23 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-30T18:01:45', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '40c0b578-ad60-4a81-b7e3-d899be8ceed3' User entered 'None (0)' | System | 30 Sep 2020 22:02:23 |
| | System | 30 Sep 2020 22:02:23 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-30T18:01:47', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '40c0b578-ad60-4a81-b7e3-d899be8ceed3' User entered 'None (0)' | System | 30 Sep 2020 22:02:23 |
| | System | 30 Sep 2020 22:02:23 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-30T18:01:50', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '40c0b578-ad60-4a81-b7e3-d899be8ceed3' User entered 'No (N)' | System | 30 Sep 2020 22:02:23 |
| | System | 30 Sep 2020 22:02:23 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-09-30T18:02:10', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '40c0b578-ad60-4a81-b7e3-d899be8ceed3' User entered '30 Sep 2020 18:02' | System | 30 Sep 2020 22:02:23 |
| | System | 30 Sep 2020 22:02:23 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '30 Sep 2020 12:00' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '01 Oct 2020 11:59' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 28 Sep 2020 18:56:49 |
| User entered 'Day 4' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-01T17:06:29', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '771ab43b-2467-473b-b5b6-2a7bab45248c' User entered 'None (0)' | System | 01 Oct 2020 21:06:48 |
| | System | 01 Oct 2020 21:06:48 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-01T17:06:31', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '771ab43b-2467-473b-b5b6-2a7bab45248c' User entered 'None (0)' | System | 01 Oct 2020 21:06:48 |
| | System | 01 Oct 2020 21:06:48 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-01T17:06:33', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '771ab43b-2467-473b-b5b6-2a7bab45248c' User entered 'None (0)' | System | 01 Oct 2020 21:06:48 |
| | System | 01 Oct 2020 21:06:48 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-01T17:06:35', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '771ab43b-2467-473b-b5b6-2a7bab45248c' User entered 'None (0)' | System | 01 Oct 2020 21:06:48 |
| | System | 01 Oct 2020 21:06:48 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-01T17:06:36', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '771ab43b-2467-473b-b5b6-2a7bab45248c' User entered 'None (0)' | System | 01 Oct 2020 21:06:48 |
| | System | 01 Oct 2020 21:06:48 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-01T17:06:38', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '771ab43b-2467-473b-b5b6-2a7bab45248c' User entered 'None (0)' | System | 01 Oct 2020 21:06:48 |
| | System | 01 Oct 2020 21:06:48 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-01T17:06:41', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '771ab43b-2467-473b-b5b6-2a7bab45248c' User entered 'No (N)' | System | 01 Oct 2020 21:06:48 |
| | System | 01 Oct 2020 21:06:48 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-01T17:06:46', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '771ab43b-2467-473b-b5b6-2a7bab45248c' User entered '01 Oct 2020 17:06' | System | 01 Oct 2020 21:06:48 |
| | System | 01 Oct 2020 21:06:48 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '01 Oct 2020 12:00' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '02 Oct 2020 11:59' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 28 Sep 2020 18:56:49 |
| User entered 'Day 5' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-02T16:46:38', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '5a0e3717-3497-46ad-83a4-8d963c0cac1b' User entered 'None (0)' | System | 02 Oct 2020 20:47:10 |
| | System | 02 Oct 2020 20:47:10 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-02T16:46:40', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '5a0e3717-3497-46ad-83a4-8d963c0cac1b' User entered 'None (0)' | System | 02 Oct 2020 20:47:10 |
| | System | 02 Oct 2020 20:47:10 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-02T16:46:41', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '5a0e3717-3497-46ad-83a4-8d963c0cac1b' User entered 'None (0)' | System | 02 Oct 2020 20:47:10 |
| | System | 02 Oct 2020 20:47:10 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-02T16:46:45', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '5a0e3717-3497-46ad-83a4-8d963c0cac1b' User entered 'None (0)' | System | 02 Oct 2020 20:47:10 |
| | System | 02 Oct 2020 20:47:10 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-02T16:46:47', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '5a0e3717-3497-46ad-83a4-8d963c0cac1b' User entered 'None (0)' | System | 02 Oct 2020 20:47:10 |
| | System | 02 Oct 2020 20:47:10 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-02T16:46:50', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '5a0e3717-3497-46ad-83a4-8d963c0cac1b' User entered 'None (0)' | System | 02 Oct 2020 20:47:10 |
| | System | 02 Oct 2020 20:47:10 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-02T16:46:55', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '5a0e3717-3497-46ad-83a4-8d963c0cac1b' User entered 'No (N)' | System | 02 Oct 2020 20:47:10 |
| | System | 02 Oct 2020 20:47:10 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-02T16:47:06', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '5a0e3717-3497-46ad-83a4-8d963c0cac1b' User entered '02 Oct 2020 16:47' | System | 02 Oct 2020 20:47:10 |
| | System | 02 Oct 2020 20:47:10 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '02 Oct 2020 12:00' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '03 Oct 2020 11:59' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 28 Sep 2020 18:56:49 |
| User entered 'Day 6' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T07:49:49', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '3fa01a38-ce11-4224-825a-b741924f4630' User entered 'None (0)' | System | 04 Oct 2020 11:50:24 |
| | System | 04 Oct 2020 11:50:24 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T07:50:14', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '3fa01a38-ce11-4224-825a-b741924f4630' | System | 04 Oct 2020 11:50:24 |
| User entered 'No interference with activity (1)' | System | 04 Oct 2020 11:50:24 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T07:49:53', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '3fa01a38-ce11-4224-825a-b741924f4630' User entered 'None (0)' | System | 04 Oct 2020 11:50:24 |
| | System | 04 Oct 2020 11:50:24 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T07:49:55', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '3fa01a38-ce11-4224-825a-b741924f4630' User entered 'None (0)' | System | 04 Oct 2020 11:50:24 |
| | System | 04 Oct 2020 11:50:24 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T07:49:57', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '3fa01a38-ce11-4224-825a-b741924f4630' User entered 'None (0)' | System | 04 Oct 2020 11:50:24 |
| | System | 04 Oct 2020 11:50:24 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T07:49:59', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '3fa01a38-ce11-4224-825a-b741924f4630' User entered 'None (0)' | System | 04 Oct 2020 11:50:24 |
| | System | 04 Oct 2020 11:50:24 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T07:50:01', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '3fa01a38-ce11-4224-825a-b741924f4630' User entered 'No (N)' | System | 04 Oct 2020 11:50:24 |
| | System | 04 Oct 2020 11:50:24 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T07:50:21', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '3fa01a38-ce11-4224-825a-b741924f4630' User entered '04 Oct 2020 07:50' | System | 04 Oct 2020 11:50:24 |
| | System | 04 Oct 2020 11:50:24 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '03 Oct 2020 12:00' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '04 Oct 2020 11:59' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 28 Sep 2020 18:56:49 |
| User entered 'Day 7' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T16:01:38', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '5e9a5733-d6f3-4fe1-8818-3f522b812ec0' User entered 'None (0)' | System | 04 Oct 2020 20:02:09 |
| | System | 04 Oct 2020 20:02:09 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T16:01:40', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '5e9a5733-d6f3-4fe1-8818-3f522b812ec0' User entered 'None (0)' | System | 04 Oct 2020 20:02:09 |
| | System | 04 Oct 2020 20:02:09 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T16:01:42', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '5e9a5733-d6f3-4fe1-8818-3f522b812ec0' User entered 'None (0)' | System | 04 Oct 2020 20:02:09 |
| | System | 04 Oct 2020 20:02:09 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T16:01:44', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '5e9a5733-d6f3-4fe1-8818-3f522b812ec0' User entered 'None (0)' | System | 04 Oct 2020 20:02:09 |
| | System | 04 Oct 2020 20:02:09 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T16:01:46', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '5e9a5733-d6f3-4fe1-8818-3f522b812ec0' User entered 'None (0)' | System | 04 Oct 2020 20:02:09 |
| | System | 04 Oct 2020 20:02:09 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T16:01:49', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '5e9a5733-d6f3-4fe1-8818-3f522b812ec0' User entered 'None (0)' | System | 04 Oct 2020 20:02:09 |
| | System | 04 Oct 2020 20:02:09 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T16:01:52', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '5e9a5733-d6f3-4fe1-8818-3f522b812ec0' User entered 'No (N)' | System | 04 Oct 2020 20:02:09 |
| | System | 04 Oct 2020 20:02:09 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-04T16:02:06', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '5e9a5733-d6f3-4fe1-8818-3f522b812ec0' User entered '04 Oct 2020 16:02' | System | 04 Oct 2020 20:02:09 |
| | System | 04 Oct 2020 20:02:09 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '04 Oct 2020 12:00' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '05 Oct 2020 11:59' | System | 28 Sep 2020 18:56:49 |

US3762120

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 04 Oct 2020 11:49:47 |
| User entered 'Day 8' | System | 04 Oct 2020 11:49:47 |

US3762120

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-05T13:48:23', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '4706d9ea-a503-41f9-b0c2-8f6da57446de' User entered 'No (N)' | System | 05 Oct 2020 17:48:33 |
| | System | 05 Oct 2020 17:48:33 |

US3762120

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 10 Jun 2021 09:41:43

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-05T13:48:28', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '4706d9ea-a503-41f9-b0c2-8f6da57446de' User entered '05 Oct 2020 13:48' | System | 05 Oct 2020 17:48:33 |
| | System | 05 Oct 2020 17:48:33 |

US3762120

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '05 Oct 2020 12:00' | System | 04 Oct 2020 11:49:47 |

US3762120

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '06 Oct 2020 11:59' | System | 04 Oct 2020 11:49:47 |

US3762120

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 04 Oct 2020 11:49:47 |
| User entered 'Day 8' | System | 04 Oct 2020 11:49:47 |

US3762120

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-05T13:48:35', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '87f9c4d6-2b08-49a6-b228-26a7e2ce686f' User entered 'No (N)' | System | 05 Oct 2020 17:48:44 |
| | System | 05 Oct 2020 17:48:44 |

US3762120

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:41:43

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-10-05T13:48:40', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '87f9c4d6-2b08-49a6-b228-26a7e2ce686f' User entered '05 Oct 2020 13:48' | System | 05 Oct 2020 17:48:44 |
| | System | 05 Oct 2020 17:48:44 |

US3762120

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:41:43

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '05 Oct 2020 12:00' | System | 04 Oct 2020 11:49:47 |

US3762120

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:41:43

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| User entered '06 Oct 2020 11:59' | System | 04 Oct 2020 11:49:47 |

US3762120

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 12 Oct 2020 18:16:21 |

US3762120

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '5 Oct 2020' | (b) (4) (b) (4), (b) (6) | 12 Oct 2020 18:16:21 |

US3762120

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 12 Oct 2020 18:16:21 |

US3762120

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 12 Oct 2020 18:16:21 |

US3762120

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 12 Oct 2020 18:16:27 |

US3762120

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'I' | System | 12 Oct 2020 18:16:27 |

US3762120

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 12 Oct 2020 18:16:49 |

US3762120

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '12 Oct 2020' | (b) (4) (b) (4), (b) (6) | 12 Oct 2020 18:16:49 |

US3762120

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 12 Oct 2020 18:16:49 |

US3762120

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 12 Oct 2020 18:16:49 |

US3762120

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 12 Oct 2020 18:16:58 |

US3762120

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'I' | System | 12 Oct 2020 18:16:58 |

US3762120

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Oct 2020 22:10:08 |

US3762120

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '19 Oct 2020' | (b) (4) (b) (4), (b) (6) | 19 Oct 2020 22:10:08 |

US3762120

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 19 Oct 2020 22:10:08 |

US3762120

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Oct 2020 22:10:08 |

US3762120

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Oct 2020 22:10:15 |

US3762120

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'I' | System | 19 Oct 2020 22:10:15 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:43

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 04 Nov 2020 19:47:48 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:43

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System). | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 10:28:19 |
| Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'correct per source' (Site from System). | Kaitlyn Van Leuvan (b) (4) | 04 Nov 2020 19:47:58 |
| User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System). | System | 04 Nov 2020 19:47:48 |
| User entered '04 Nov 2020' | Kaitlyn Van Leuvan (b) (4) | 04 Nov 2020 19:47:48 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:43

[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 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Clinic (Clinic)' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 04 Nov 2020 19:47:48 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:43

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'VISIT3' | System | 04 Nov 2020 19:47:48 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 04 Nov 2020 19:48:43 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '04 Nov 2020' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 04 Nov 2020 19:48:43 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '09:21' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 04 Nov 2020 19:48:43 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered '04 Nov 2020 09:21' | System | 04 Nov 2020 19:48:43 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '97.7' F | (b) (4) Kaitlyn Van Leuvan (b) (4) | 04 Nov 2020 19:48:43 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Oral (Oral)' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 04 Nov 2020 19:48:43 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | (b) (4) Kaitlyn Van Leuvan (b) (4) | 04 Nov 2020 19:48:43 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '58' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 04 Nov 2020 19:48:43 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'bpm' | System | 04 Nov 2020 19:48:43 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '14' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 04 Nov 2020 19:48:43 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'breaths/min' | System | 04 Nov 2020 19:48:43 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '112' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 04 Nov 2020 19:48:43 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'mmHg' | System | 04 Nov 2020 19:48:43 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '72' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 04 Nov 2020 19:48:43 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'mmHg' | System | 04 Nov 2020 19:48:43 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| | | |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:43

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'No (N)' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 04 Nov 2020 19:49:17 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:43

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered empty. | Kaitlyn Van Leuvan (b) (4) | 04 Nov 2020 19:49:17 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:43

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 04 Nov 2020 19:49:36 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:43

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '04 Nov 2020' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 04 Nov 2020 19:49:36 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:43

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered '09:40' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 04 Nov 2020 19:49:36 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:43

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered '04 Nov 2020 09:40' | System | 04 Nov 2020 19:49:36 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 12 Feb 2021 22:57:31 |
| User entered 'Yes (Y)' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 04 Nov 2020 19:49:40 |

US3762120

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'I' | System | 04 Nov 2020 19:49:40 |

US3762120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 64' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-11-04T12:14:41', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '80d88089-35a8-43bc-9cc6-5fad60b2f059' | System | 04 Nov 2020 17:14:56 |
| User entered 'No (N)' | System | 04 Nov 2020 17:14:56 |

US3762120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-11-04T12:14:44', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '80d88089-35a8-43bc-9cc6-5fad60b2f059' | System | 04 Nov 2020 17:14:56 |
| User entered 'No (N)' | System | 04 Nov 2020 17:14:56 |

US3762120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-11-04T12:14:51', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '80d88089-35a8-43bc-9cc6-5fad60b2f059' User entered '04 Nov 2020 12:14:51' | System | 04 Nov 2020 17:14:56 |
| | System | 04 Nov 2020 17:14:56 |

US3762120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered '31 Oct 2020 00:01' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered '04 Nov 2020 23:59' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 71' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-11-11T07:15:31', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'e2a32030-50bb-43be-b7f8-5da9f2eb7968' | System | 11 Nov 2020 12:15:49 |
| User entered 'No (N)' | System | 11 Nov 2020 12:15:49 |

US3762120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-11-11T07:15:40', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'e2a32030-50bb-43be-b7f8-5da9f2eb7968' | System | 11 Nov 2020 12:15:49 |
| User entered 'No (N)' | System | 11 Nov 2020 12:15:49 |

US3762120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-11-11T07:15:47', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'e2a32030-50bb-43be-b7f8-5da9f2eb7968' User entered '11 Nov 2020 07:15:47' | System | 11 Nov 2020 12:15:49 |
| | System | 11 Nov 2020 12:15:49 |

US3762120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered '07 Nov 2020 00:01' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered '11 Nov 2020 23:59' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered 'Day 78' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-11-14T08:43:33', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '8dd17502-c1bb-42fb-9f59-0508fa5a47f2' | System | 14 Nov 2020 13:43:46 |
| User entered 'No (N)' | System | 14 Nov 2020 13:43:46 |

US3762120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-11-14T08:43:36', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '8dd17502-c1bb-42fb-9f59-0508fa5a47f2' | System | 14 Nov 2020 13:43:46 |
| User entered 'No (N)' | System | 14 Nov 2020 13:43:46 |

US3762120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-11-14T08:43:44', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '8dd17502-c1bb-42fb-9f59-0508fa5a47f2' User entered '14 Nov 2020 08:43:44' | System | 14 Nov 2020 13:43:46 |
| | System | 14 Nov 2020 13:43:46 |

US3762120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered '14 Nov 2020 00:01' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:10:43 |
| Data entry locked. | System | 31 Aug 2020 20:22:26 |
| User entered '18 Nov 2020 23:59' | System | 31 Aug 2020 20:22:26 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 82' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '18 Nov 2020 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '22 Nov 2020 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 89' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-11-28T07:46:29', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '56a33ada-cd8e-4c5a-8e5d-3e91f8bd49e1' User entered 'No (N)' | System | 28 Nov 2020 12:46:49 |
| | System | 28 Nov 2020 12:46:49 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

Have you been exposed to someone with 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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-11-28T07:46:33', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '56a33ada-cd8e-4c5a-8e5d-3e91f8bd49e1' User entered 'No (N)' | System | 28 Nov 2020 12:46:49 |
| | System | 28 Nov 2020 12:46:49 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-11-28T07:46:47', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '56a33ada-cd8e-4c5a-8e5d-3e91f8bd49e1' User entered '28 Nov 2020 07:46:47' | System | 28 Nov 2020 12:46:49 |
| | System | 28 Nov 2020 12:46:49 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '25 Nov 2020 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '29 Nov 2020 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-12-02T08:00:13', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'b8cc3abc-f3fd-48e2-acfe-1e5649bac50a' User entered 'No (N)' | System | 02 Dec 2020 13:00:30 |
| | System | 02 Dec 2020 13:00:30 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

Have you been exposed to someone with 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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-12-02T08:00:18', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'b8cc3abc-f3fd-48e2-acfe-1e5649bac50a' User entered 'No (N)' | System | 02 Dec 2020 13:00:30 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-12-02T08:00:28', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'b8cc3abc-f3fd-48e2-acfe-1e5649bac50a' User entered '02 Dec 2020 08:00:28' | System | 02 Dec 2020 13:00:30 |
| | System | 02 Dec 2020 13:00:30 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '02 Dec 2020 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '06 Dec 2020 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-12-09T11:11:40', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '5814604f-5d04-4aaa-a203-0e616b2479cf' User entered 'No (N)' | System | 09 Dec 2020 16:12:01 |
| | System | 09 Dec 2020 16:12:01 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

Have you been exposed to someone with 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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-12-09T11:11:48', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '5814604f-5d04-4aaa-a203-0e616b2479cf' User entered 'No (N)' | System | 09 Dec 2020 16:12:01 |
| | System | 09 Dec 2020 16:12:01 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-12-09T11:11:58', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '5814604f-5d04-4aaa-a203-0e616b2479cf' User entered '09 Dec 2020 11:11:58' | System | 09 Dec 2020 16:12:01 |
| | System | 09 Dec 2020 16:12:01 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '09 Dec 2020 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '13 Dec 2020 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-12-16T10:55:39', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f18f8b50-b23e-4186-836a-2f39f04437a8' User entered 'No (N)' | System | 16 Dec 2020 15:55:56 |
| | System | 16 Dec 2020 15:55:56 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

Have you been exposed to someone with 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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-12-16T10:55:46', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f18f8b50-b23e-4186-836a-2f39f04437a8' | System | 16 Dec 2020 15:55:56 |
| User entered 'No (N)' | System | 16 Dec 2020 15:55:56 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-12-16T10:55:54', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f18f8b50-b23e-4186-836a-2f39f04437a8' User entered '16 Dec 2020 10:55:54' | System | 16 Dec 2020 15:55:56 |
| | System | 16 Dec 2020 15:55:56 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '16 Dec 2020 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '20 Dec 2020 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-12-23T08:30:59', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '759dd663-66a2-4f0a-ab07-21eb86eb5989' User entered 'No (N)' | System | 23 Dec 2020 13:31:12 |
| | System | 23 Dec 2020 13:31:12 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

Have you been exposed to someone with 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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-12-23T08:31:03', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '759dd663-66a2-4f0a-ab07-21eb86eb5989' User entered 'No (N)' | System | 23 Dec 2020 13:31:12 |
| | System | 23 Dec 2020 13:31:12 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-12-23T08:31:10', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '759dd663-66a2-4f0a-ab07-21eb86eb5989' User entered '23 Dec 2020 08:31:10' | System | 23 Dec 2020 13:31:12 |
| | System | 23 Dec 2020 13:31:12 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '23 Dec 2020 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '27 Dec 2020 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-12-31T10:07:08', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'b06517a7-01ea-420f-91b9-148e793a74f6' User entered 'No (N)' | System | 31 Dec 2020 15:07:23 |
| | System | 31 Dec 2020 15:07:23 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

Have you been exposed to someone with 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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-12-31T10:07:12', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'b06517a7-01ea-420f-91b9-148e793a74f6' User entered 'No (N)' | System | 31 Dec 2020 15:07:23 |
| | System | 31 Dec 2020 15:07:23 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2020-12-31T10:07:20', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'b06517a7-01ea-420f-91b9-148e793a74f6' User entered '31 Dec 2020 10:07:20' | System | 31 Dec 2020 15:07:23 |
| | System | 31 Dec 2020 15:07:23 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '30 Dec 2020 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '03 Jan 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-01-07T09:10:08', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'edb95b84-63dc-4048-a3ee-bc8525006b7e' User entered 'No (N)' | System | 07 Jan 2021 14:10:23 |
| | System | 07 Jan 2021 14:10:23 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

Have you been exposed to someone with 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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-01-07T09:10:12', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'edb95b84-63dc-4048-a3ee-bc8525006b7e' | System | 07 Jan 2021 14:10:23 |
| User entered 'No (N)' | System | 07 Jan 2021 14:10:23 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-01-07T09:10:19', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'edb95b84-63dc-4048-a3ee-bc8525006b7e' User entered '07 Jan 2021 09:10:19' | System | 07 Jan 2021 14:10:23 |
| | System | 07 Jan 2021 14:10:23 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '06 Jan 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '10 Jan 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-01-15T11:54:36', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '15168b05-868f-4249-ab08-5da40b3f69d1' | System | 15 Jan 2021 16:54:51 |
| User entered 'No (N)' | System | 15 Jan 2021 16:54:51 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

Have you been exposed to someone with 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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-01-15T11:54:38', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '15168b05-868f-4249-ab08-5da40b3f69d1' | System | 15 Jan 2021 16:54:51 |
| User entered 'No (N)' | System | 15 Jan 2021 16:54:51 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-01-15T11:54:44', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '15168b05-868f-4249-ab08-5da40b3f69d1' User entered '15 Jan 2021 11:54:44' | System | 15 Jan 2021 16:54:51 |
| | System | 15 Jan 2021 16:54:51 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '13 Jan 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '17 Jan 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-01-21T07:28:14', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '85aa9fa6-3283-467d-adf9-f0ee2e2dfc43' | System | 21 Jan 2021 12:29:22 |
| User entered 'No (N)' | System | 21 Jan 2021 12:29:22 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

Have you been exposed to someone with 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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-01-21T07:29:14', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '85aa9fa6-3283-467d-adf9-f0ee2e2dfc43' User entered 'No (N)' | System | 21 Jan 2021 12:29:22 |
| | System | 21 Jan 2021 12:29:22 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-01-21T07:29:18', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '85aa9fa6-3283-467d-adf9-f0ee2e2dfc43' | System | 21 Jan 2021 12:29:22 |
| User entered '21 Jan 2021 07:29:18' | System | 21 Jan 2021 12:29:22 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '20 Jan 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '24 Jan 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-01-27T08:11:23', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'ba094987-703f-4574-a12a-788da80c08d2' | System | 27 Jan 2021 13:11:37 |
| User entered 'No (N)' | System | 27 Jan 2021 13:11:37 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

Have you been exposed to someone with 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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-01-27T08:11:27', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'ba094987-703f-4574-a12a-788da80c08d2' | System | 27 Jan 2021 13:11:37 |
| User entered 'No (N)' | System | 27 Jan 2021 13:11:37 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-01-27T08:11:35', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'ba094987-703f-4574-a12a-788da80c08d2' User entered '27 Jan 2021 08:11:35' | System | 27 Jan 2021 13:11:37 |
| | System | 27 Jan 2021 13:11:37 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '27 Jan 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '31 Jan 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-02-04T12:30:02', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f4c25154-0c31-4408-84fa-cd8403d43a32' | System | 04 Feb 2021 17:30:18 |
| User entered 'No (N)' | System | 04 Feb 2021 17:30:18 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

Have you been exposed to someone with 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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-02-04T12:30:05', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f4c25154-0c31-4408-84fa-cd8403d43a32' | System | 04 Feb 2021 17:30:18 |
| User entered 'No (N)' | System | 04 Feb 2021 17:30:18 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-02-04T12:30:13', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f4c25154-0c31-4408-84fa-cd8403d43a32' User entered '04 Feb 2021 12:30:13' | System | 04 Feb 2021 17:30:18 |
| | System | 04 Feb 2021 17:30:18 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '03 Feb 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '07 Feb 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-02-10T07:53:36', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '643b1932-9c3e-4ac4-8433-860c272240b8' | System | 10 Feb 2021 12:53:49 |
| User entered 'No (N)' | System | 10 Feb 2021 12:53:49 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

Have you been exposed to someone with 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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-02-10T07:53:40', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '643b1932-9c3e-4ac4-8433-860c272240b8' User entered 'No (N)' | System | 10 Feb 2021 12:53:49 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-02-10T07:53:47', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '643b1932-9c3e-4ac4-8433-860c272240b8' User entered '10 Feb 2021 07:53:47' | System | 10 Feb 2021 12:53:49 |
| | System | 10 Feb 2021 12:53:49 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '10 Feb 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '14 Feb 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-02-18T12:42:40', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '6052fee3-7d65-4045-b4e7-92ec96c4011d' User entered 'No (N)' | System | 18 Feb 2021 17:42:53 |
| | System | 18 Feb 2021 17:42:53 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

Have you been exposed to someone with 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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-02-18T12:42:43', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '6052fee3-7d65-4045-b4e7-92ec96c4011d' User entered 'No (N)' | System | 18 Feb 2021 17:42:53 |
| | System | 18 Feb 2021 17:42:53 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-02-18T12:42:47', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '6052fee3-7d65-4045-b4e7-92ec96c4011d' User entered '18 Feb 2021 12:42:47' | System | 18 Feb 2021 17:42:53 |
| | System | 18 Feb 2021 17:42:53 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '17 Feb 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '21 Feb 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-02-24T08:44:26-05:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '4c210fab-c9a9-4d57-9933-9899e60e449d' User entered 'Yes (Y)' | System | 24 Feb 2021 13:45:31 |
| | System | 24 Feb 2021 13:45:31 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

Have you been exposed to someone with 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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-02-24T08:44:36-05:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '4c210fab-c9a9-4d57-9933-9899e60e449d' User entered 'No (N)' | System | 24 Feb 2021 13:45:31 |
| | System | 24 Feb 2021 13:45:31 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-02-24T08:44:43-05:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '4c210fab-c9a9-4d57-9933-9899e60e449d' User entered 'No (N)' | System | 24 Feb 2021 13:45:31 |
| | System | 24 Feb 2021 13:45:31 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-02-24T08:44:50-05:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '4c210fab-c9a9-4d57-9933-9899e60e449d' User entered 'Yes (Y)' | System | 24 Feb 2021 13:45:31 |
| | System | 24 Feb 2021 13:45:31 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

Please 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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-02-24T08:45:10-05:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '4c210fab-c9a9-4d57-9933-9899e60e449d' | System | 24 Feb 2021 13:45:31 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 24 Feb 2021 13:45:31 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-02-24T08:45:20-05:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '4c210fab-c9a9-4d57-9933-9899e60e449d' User entered '24 Feb 2021 13:45:20' | System | 24 Feb 2021 13:45:31 |
| | System | 24 Feb 2021 13:45:31 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '24 Feb 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '28 Feb 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-03-03T06:22:14-05:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'ed998db4-b3c0-4fa7-976c-936170e784eb' | System | 03 Mar 2021 11:22:26 |
| User entered 'No (N)' | System | 03 Mar 2021 11:22:26 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

Have you been exposed to someone with 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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-03-03T06:22:18-05:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'ed998db4-b3c0-4fa7-976c-936170e784eb' User entered 'No (N)' | System | 03 Mar 2021 11:22:26 |
| | System | 03 Mar 2021 11:22:26 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-03-03T06:22:23-05:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'ed998db4-b3c0-4fa7-976c-936170e784eb' User entered '03 Mar 2021 06:22:23' | System | 03 Mar 2021 11:22:26 |
| | System | 03 Mar 2021 11:22:26 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '03 Mar 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '07 Mar 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-03-10T07:09:10-05:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '3007635b-2eec-4212-a5db-10d6bd5e5d4f' | System | 10 Mar 2021 12:09:28 |
| User entered 'No (N)' | System | 10 Mar 2021 12:09:28 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

Have you been exposed to someone with 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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-03-10T07:09:17-05:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '3007635b-2eec-4212-a5db-10d6bd5e5d4f' User entered 'No (N)' | System | 10 Mar 2021 12:09:28 |
| | System | 10 Mar 2021 12:09:28 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-03-10T07:09:24-05:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '3007635b-2eec-4212-a5db-10d6bd5e5d4f' User entered '10 Mar 2021 07:09:24' | System | 10 Mar 2021 12:09:28 |
| | System | 10 Mar 2021 12:09:28 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '10 Mar 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '14 Mar 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-03-17T09:39:02-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '91e7e166-946f-4a7f-b3a6-4469c413fa76' | System | 17 Mar 2021 13:40:01 |
| User entered 'Yes (Y)' | System | 17 Mar 2021 13:40:01 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

Have you been exposed to someone with 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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-03-17T09:39:00-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '91e7e166-946f-4a7f-b3a6-4469c413fa76' | System | 17 Mar 2021 13:40:01 |
| User entered 'No (N)' | System | 17 Mar 2021 13:40:01 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-03-17T09:38:54-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '91e7e166-946f-4a7f-b3a6-4469c413fa76' | System | 17 Mar 2021 13:40:01 |
| User entered 'No (N)' | System | 17 Mar 2021 13:40:01 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-03-17T09:39:10-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '91e7e166-946f-4a7f-b3a6-4469c413fa76' | System | 17 Mar 2021 13:40:01 |
| User entered 'Yes (Y)' | System | 17 Mar 2021 13:40:01 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Please 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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-03-17T09:39:34-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '91e7e166-946f-4a7f-b3a6-4469c413fa76' | System | 17 Mar 2021 13:40:01 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 17 Mar 2021 13:40:01 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-03-17T09:39:49-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '91e7e166-946f-4a7f-b3a6-4469c413fa76' | System | 17 Mar 2021 13:40:01 |
| User entered '17 Mar 2021 09:39:49' | System | 17 Mar 2021 13:40:01 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '17 Mar 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '21 Mar 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-03-24T09:34:48-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'eaa803d5-3908-4abf-a0fd-382db4b8f507' | System | 24 Mar 2021 13:34:57 |
| User entered 'No (N)' | System | 24 Mar 2021 13:34:57 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

Have you been exposed to someone with 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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-03-24T09:34:51-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'eaa803d5-3908-4abf-a0fd-382db4b8f507' | System | 24 Mar 2021 13:34:57 |
| User entered 'No (N)' | System | 24 Mar 2021 13:34:57 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-03-24T09:34:55-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'eaa803d5-3908-4abf-a0fd-382db4b8f507' | System | 24 Mar 2021 13:34:57 |
| User entered '24 Mar 2021 09:34:55' | System | 24 Mar 2021 13:34:57 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '24 Mar 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '28 Mar 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-03-31T19:02:19-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '0c1bc606-c87e-4680-8eec-b4b8063d1805' | System | 31 Mar 2021 23:04:56 |
| User entered 'No (N)' | System | 31 Mar 2021 23:04:56 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

Have you been exposed to someone with 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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-03-31T19:02:23-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '0c1bc606-c87e-4680-8eec-b4b8063d1805' | System | 31 Mar 2021 23:04:56 |
| User entered 'No (N)' | System | 31 Mar 2021 23:04:56 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-03-31T19:02:27-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '0c1bc606-c87e-4680-8eec-b4b8063d1805' User entered '31 Mar 2021 19:02:27' | System | 31 Mar 2021 23:04:56 |
| | System | 31 Mar 2021 23:04:56 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '31 Mar 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '04 Apr 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-04-07T06:59:57-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'b7b53d25-29b6-442d-b2c6-7febfe5c5b64' | System | 07 Apr 2021 11:00:09 |
| User entered 'No (N)' | System | 07 Apr 2021 11:00:09 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

Have you been exposed to someone with 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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-04-07T07:00:01-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'b7b53d25-29b6-442d-b2c6-7febf5c5b64' | System | 07 Apr 2021 11:00:09 |
| User entered 'No (N)' | System | 07 Apr 2021 11:00:09 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-04-07T07:00:07-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'b7b53d25-29b6-442d-b2c6-7febf5c5b64' | System | 07 Apr 2021 11:00:09 |
| User entered '07 Apr 2021 07:00:07' | System | 07 Apr 2021 11:00:09 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '07 Apr 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '11 Apr 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-04-14T07:20:34-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '3a732f73-6a12-4ca2-90cc-dd42435c3bd1' | System | 23 Apr 2021 16:02:41 |
| User entered 'No (N)' | System | 23 Apr 2021 16:02:41 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

Have you been exposed to someone with 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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-04-14T07:20:37-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '3a732f73-6a12-4ca2-90cc-dd42435c3bd1' | System | 23 Apr 2021 16:02:41 |
| User entered 'No (N)' | System | 23 Apr 2021 16:02:41 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-04-14T07:20:42-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '3a732f73-6a12-4ca2-90cc-dd42435c3bd1' | System | 23 Apr 2021 16:02:41 |
| User entered '14 Apr 2021 07:20:42' | System | 23 Apr 2021 16:02:41 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '14 Apr 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '18 Apr 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-04-23T12:00:52-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '9a8af406-4549-4cdc-81fb-d7f0f17d0e37' | System | 23 Apr 2021 16:04:11 |
| User entered 'No (N)' | System | 23 Apr 2021 16:04:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

Have you been exposed to someone with 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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-04-23T12:00:56-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '9a8af406-4549-4cdc-81fb-d7f0f17d0e37' | System | 23 Apr 2021 16:04:11 |
| User entered 'No (N)' | System | 23 Apr 2021 16:04:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-04-23T12:01:00-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '9a8af406-4549-4cdc-81fb-d7f0f17d0e37' | System | 23 Apr 2021 16:04:11 |
| User entered '23 Apr 2021 12:01:00' | System | 23 Apr 2021 16:04:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '21 Apr 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '25 Apr 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-05-01T07:15:37-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '1bdf1ce2-04ca-4823-9154-bfc4424393d0' | System | 01 May 2021 11:15:48 |
| User entered 'No (N)' | System | 01 May 2021 11:15:48 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

Have you been exposed to someone with 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 (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-05-01T07:15:39-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '1bdf1ce2-04ca-4823-9154-bfc4424393d0' | System | 01 May 2021 11:15:48 |
| User entered 'No (N)' | System | 01 May 2021 11:15:48 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-05-01T07:15:44-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: '1bdf1ce2-04ca-4823-9154-bfc4424393d0' | System | 01 May 2021 11:15:48 |
| User entered '01 May 2021 07:15:44' | System | 01 May 2021 11:15:48 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '28 Apr 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '02 May 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '05 May 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '09 May 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '12 May 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '16 May 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '19 May 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '23 May 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '26 May 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '30 May 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '02 Jun 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '06 Jun 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '09 Jun 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '13 Jun 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '16 Jun 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '20 Jun 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '23 Jun 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '27 Jun 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '30 Jun 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '04 Jul 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '07 Jul 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '11 Jul 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '14 Jul 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '18 Jul 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '21 Jul 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '25 Jul 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '28 Jul 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '01 Aug 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '04 Aug 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '08 Aug 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '11 Aug 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '15 Aug 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '18 Aug 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '22 Aug 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '25 Aug 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '29 Aug 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '01 Sep 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '05 Sep 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '08 Sep 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '12 Sep 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '15 Sep 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '19 Sep 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '22 Sep 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '26 Sep 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '29 Sep 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '03 Oct 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '06 Oct 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '10 Oct 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '13 Oct 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '17 Oct 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '20 Oct 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '24 Oct 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '27 Oct 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '31 Oct 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '03 Nov 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '07 Nov 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '10 Nov 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '14 Nov 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '17 Nov 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '21 Nov 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '24 Nov 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '28 Nov 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '01 Dec 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '05 Dec 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '08 Dec 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '12 Dec 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '15 Dec 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '19 Dec 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '22 Dec 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '26 Dec 2021 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '29 Dec 2021 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '02 Jan 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '05 Jan 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '09 Jan 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '12 Jan 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '16 Jan 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '19 Jan 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '23 Jan 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '26 Jan 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '30 Jan 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '02 Feb 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '06 Feb 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '09 Feb 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '13 Feb 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '16 Feb 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '20 Feb 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '23 Feb 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '27 Feb 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '02 Mar 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '06 Mar 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '09 Mar 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '13 Mar 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '16 Mar 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '20 Mar 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '23 Mar 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '27 Mar 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '30 Mar 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '03 Apr 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '06 Apr 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '10 Apr 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '13 Apr 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '17 Apr 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '20 Apr 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '24 Apr 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '27 Apr 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '01 May 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '04 May 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '08 May 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '11 May 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '15 May 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '18 May 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '22 May 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '25 May 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '29 May 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '01 Jun 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '05 Jun 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '08 Jun 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '12 Jun 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '15 Jun 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '19 Jun 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '22 Jun 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '26 Jun 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '29 Jun 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '03 Jul 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '06 Jul 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '10 Jul 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '13 Jul 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '17 Jul 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '20 Jul 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '24 Jul 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '27 Jul 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '31 Jul 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '03 Aug 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '07 Aug 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '10 Aug 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '14 Aug 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '17 Aug 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '21 Aug 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '24 Aug 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '28 Aug 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '31 Aug 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '04 Sep 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '07 Sep 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '11 Sep 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '14 Sep 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '18 Sep 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '21 Sep 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '25 Sep 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '28 Sep 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '02 Oct 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '05 Oct 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '09 Oct 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '12 Oct 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '16 Oct 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '19 Oct 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '23 Oct 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '26 Oct 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '30 Oct 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '02 Nov 2022 00:01' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:43

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:15:11 |
| Amendment Manager: User entered '06 Nov 2022 23:59' | System | 19 Nov 2020 21:15:11 |

US3762120

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:41:43

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 18:35:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-03-29T13:35:04-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f250ffe5-8e47-474d-8aa8-da70a4004c5e' | System | 29 Mar 2021 17:35:15 |
| User entered 'No (N)' | System | 29 Mar 2021 17:35:15 |

US3762120

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:41:43

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 18:35:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AB06766-7EBA-43EC-BE55-BFC068098285)', Time: '2021-03-29T13:35:12-04:00', User OID: 'PatientReportedOutcome (US3762120)', ODM File OID: 'f250ffe5-8e47-474d-8aa8-da70a4004c5e' | System | 29 Mar 2021 17:35:15 |
| User entered '29 Mar 2021 13:35:12' | System | 29 Mar 2021 17:35:15 |

US3762120

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 08 Mar 2021 18:30:06 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 18:57:51 |

US3762120

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 08 Mar 2021 18:30:06 |
| User entered '23 Nov 2020' | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 18:57:51 |

US3762120

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 08 Mar 2021 18:30:06 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 18:57:51 |

US3762120

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 08 Mar 2021 18:30:06 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 18:57:51 |

US3762120

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User signature succeeded. | John Sanders (b) (4) | 08 Mar 2021 18:30:06 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 18:58:00 |

US3762120

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 16:23:46 |
| User entered 'I' | System | 23 Nov 2020 18:58:00 |

US3762120

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:50:11 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'Yes (Y)' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 05 Jan 2021 21:49:08 |

US3762120

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:50:11 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '29 Dec 2020' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 05 Jan 2021 21:49:08 |

US3762120

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:50:11 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 05 Jan 2021 21:49:08 |

US3762120

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:50:11 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4) Kaitlyn Van Leuvan (b) (4) | 05 Jan 2021 21:49:08 |

US3762120

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:50:11 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'Yes (Y)' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 05 Jan 2021 21:49:13 |

US3762120

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:50:11 |
| User entered 'I' | System | 05 Jan 2021 21:49:13 |

US3762120

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:50:11 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 19:18:57 |

US3762120

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:50:11 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '25 Jan 2021' | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 19:18:57 |

US3762120

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:50:11 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 19:18:57 |

US3762120

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:50:11 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 19:18:57 |

US3762120

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:50:11 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 19:19:04 |

US3762120

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:50:11 |
| User entered 'I' | System | 25 Jan 2021 19:19:04 |

US3762120

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:50:11 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 16:48:46 |

US3762120

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:50:11 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '22 Feb 2021' | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 16:48:46 |

US3762120

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:50:11 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 16:48:46 |

US3762120

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:43

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:50:11 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 16:48:46 |

US3762120

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:50:11 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 16:48:53 |

US3762120

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:50:11 |
| User entered 'I' | System | 04 Mar 2021 16:48:53 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:43

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 29 Mar 2021 18:55:30 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '29 Mar 2021' | (b) (4) (b) (4), (b) (6) | 29 Mar 2021 18:55:30 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 29 Mar 2021 18:55:30 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:43

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'VISIT4' | System | 29 Mar 2021 18:55:30 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 29 Mar 2021 18:55:39 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 29 Mar 2021 18:55:39 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 29 Mar 2021 18:55:39 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Mar 2021 18:55:39 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 29 Mar 2021 18:55:39 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 29 Mar 2021 18:55:39 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 29 Mar 2021 18:55:39 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 29 Mar 2021 18:55:39 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Mar 2021 18:55:39 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 29 Mar 2021 18:55:39 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Mar 2021 18:55:39 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 29 Mar 2021 18:55:39 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Mar 2021 18:55:39 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 29 Mar 2021 18:55:39 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:43

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Mar 2021 18:55:39 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:43

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 29 Mar 2021 18:55:45 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:43

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 29 Mar 2021 18:55:45 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:43

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 29 Mar 2021 18:56:11 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:43

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '29 Mar 2021' | (b) (4) (b) (4), (b) (6) | 29 Mar 2021 18:56:11 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:43

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '13:41' | (b) (4) (b) (4), (b) (6) | 29 Mar 2021 18:56:11 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:43

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Mar 2021 13:41' | System | 29 Mar 2021 18:56:11 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 29 Mar 2021 18:56:15 |

US3762120

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:43

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 29 Mar 2021 18:56:15 |

US3762120

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

Form: Visit Date

Generated On: 10 Jun 2021 09:41:43

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:24:08 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'Yes (Y)' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 30 Dec 2020 21:34:35 |

US3762120

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

Form: Visit Date

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:24:08 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '30 Dec 2020' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 30 Dec 2020 21:34:35 |

US3762120

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

Form: Visit Date

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:24:08 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'Clinic (Clinic)' | Kaitlyn Van Leuvan (b) (4) | 30 Dec 2020 21:34:35 |

US3762120

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

Form: Visit Date

Generated On: 10 Jun 2021 09:41:43

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:24:08 |
| User entered 'UNBLND_DECIDE' | System | 30 Dec 2020 21:34:35 |

US3762120

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

Form: Unblinding

Generated On: 10 Jun 2021 09:41:43

[Date of updated informed consent \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:24:08 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '30 Dec 2020' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 30 Dec 2020 21:35:16 |

US3762120

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

Form: Unblinding

Generated On: 10 Jun 2021 09:41:43

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:24:08 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '0' WR# 5295537 | (b) (4) | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 18:07:28 |

US3762120

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

Form: Unblinding

Generated On: 10 Jun 2021 09:41:43

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:24:08 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'Yes (Y)' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 30 Dec 2020 21:35:16 |

US3762120

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

Form: Unblinding

Generated On: 10 Jun 2021 09:41:43

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:24:08 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537 | (b) (4) | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 18:07:28 |

US3762120

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

Form: Unblinding

Generated On: 10 Jun 2021 09:41:43

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:24:08 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '30 Dec 2020' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 30 Dec 2020 21:35:16 |

US3762120

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

Form: Unblinding

Generated On: 10 Jun 2021 09:41:43

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|--------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:24:08 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 30 Dec 2020 21:35:16 |

US3762120

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

Form: Unblinding

Generated On: 10 Jun 2021 09:41:43

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:24:08 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)' | (b) (4) | 20 Jan 2021 13:32:29 |
| User entered 'mRNA-1273 (mRNA-1273)' | Kaitlyn Van Leuvan (b) (4) | 30 Dec 2020 21:35:16 |

US3762120

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

Form: Unblinding

Generated On: 10 Jun 2021 09:41:43

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:24:08 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)' | (b) (4) | 20 Jan 2021 13:32:29 |
| User entered 'mRNA-1273 (mRNA-1273)' | Kaitlyn Van Leuvan (b) (4) | 30 Dec 2020 21:35:16 |

US3762120

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

Form: Unblinding

Generated On: 10 Jun 2021 09:41:43

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:24:08 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'No (N)' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 30 Dec 2020 21:35:16 |

US3762120

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

Form: Unblinding

Generated On: 10 Jun 2021 09:41:43

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:24:08 |
| User entered empty. | System | 30 Dec 2020 21:35:16 |

US3762120

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

Form: Unblinding

Generated On: 10 Jun 2021 09:41:43

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:24:08 |
| User entered empty. | System | 30 Dec 2020 21:35:16 |

US3762120

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:43

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:24:08 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'Yes (Y)' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 30 Dec 2020 21:35:42 |

US3762120

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:43

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:24:08 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '30 Dec 2020' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 30 Dec 2020 21:35:42 |

US3762120

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:43

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:24:08 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '14:58' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 30 Dec 2020 21:35:42 |

US3762120

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:43

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:24:08 |
| User entered '30 Dec 2020 14:58' | System | 30 Dec 2020 21:35:42 |

US3762120

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:41:43

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:24:08 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'Yes (Y)' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 30 Dec 2020 21:36:18 |

US3762120

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:24:08 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '30 Dec 2020' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 30 Dec 2020 21:36:18 |

US3762120

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:41:43

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:24:08 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '15:00' | (b) (4) Kaitlyn Van Leuvan (b) (4) | 30 Dec 2020 21:36:18 |

US3762120

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:41:43

[Collection Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:24:08 |
| User entered '30 Dec 2020 15:00' | System | 30 Dec 2020 21:36:18 |

US3762120

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:41:43

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 05:37:03 |
| User signature succeeded. | John Sanders (b) (4) | 23 Mar 2021 17:28:29 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:47 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Feb 2021 16:57:05 |
| User entered 'No (N)' | (b) (4), (b) (6) | 10 Feb 2021 15:52:00 |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[AEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 03 Mar 2021 20:01:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered | System | 22 Feb 2021 19:21:18 |
| 'USA-US130-2021-mRNA-1273-P301000005' | | |
| User entered 'New' | (b) (4), (b) (6) | 22 Feb 2021 19:21:18 |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 18:59:51 |
| User closed query 'PV Query: The event term nephrolithiasis with complicated urinary tract infection contains multiple event terms. Please consider separating them into separate events.' (Site from Safety). | (b) (4), (b) (6) | 24 Mar 2021 22:35:32 |
| User coded data point as SOC: Renal and urinary disorders, HLT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis - version MedDRA\23.0. | Coder Import (b) (4) | 24 Mar 2021 21:25:42 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | (b) (4) | 24 Mar 2021 21:25:42 |
| Data point term sent to Coder | System | 24 Mar 2021 21:25:15 |
| User closed query 'CDM Coding, please split the term (NEPHROLITHIASIS WITH COMPLICATED URINARY TRACT INFECTION) into two separate records, as 'NEPHROLITHIASIS' and 'COMPLICATED URINARY TRACT INFECTION' reporting each term separately with all relevant information e.g. start and stop dates etc. ' (Site from System). | System | 24 Mar 2021 21:24:48 |
| Query 'CDM Coding, please split the term (NEPHROLITHIASIS WITH COMPLICATED URINARY TRACT INFECTION) into two separate records, as 'NEPHROLITHIASIS' and 'COMPLICATED URINARY TRACT INFECTION' reporting each term separately with all relevant information e.g. start and stop dates etc. ' answered with 'updated into two separate terms ' (Site from System). | (b) (4), (b) (6) | 24 Mar 2021 21:24:48 |
| Query 'PV Query: The event term nephrolithiasis with complicated urinary tract infection contains multiple event terms. Please consider separating them into separate events.' answered with 'updated into separate events on AE log ' (Site from Safety). | (b) (4), (b) (6) | 24 Mar 2021 21:24:37 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 24 Mar 2021 21:24:21 |
| User entered 'NEPHROLITHIASIS' reason for change: Data Entry Error | (b) (4), (b) (6) | 24 Mar 2021 21:24:21 |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User opened query 'CDM Coding, please split the term (NEPHROLITHIASIS WITH COMPLICATED URINARY TRACT INFECTION) into two separate records, as 'NEPHROLITHIASIS' and 'COMPLICATED URINARY TRACT INFECTION' reporting each term separately with all relevant information e.g. start and stop dates etc. ' (Site from System). | Coder Import (b) (4) (b) (4) | 18 Mar 2021 18:01:41 |
| User opened query 'PV Query: The event term nephrolithiasis with complicated urinary tract infection contains multiple event terms. Please consider separating them into separate events.' (Site from Safety). | (b) (4), (b) (6) | 03 Mar 2021 20:02:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| Data point term sent to Coder | System | 22 Feb 2021 18:20:16 |
| Coding entries removed. | (b) (4), (b) (6) | 22 Feb 2021 18:19:20 |
| User entered 'NEPHROLITHIASIS with complicated urinary tract infection' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Feb 2021 18:19:20 |
| User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Feb 2021 17:00:01 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Feb 2021 17:00:01 |
| Data point term sent to Coder | System | 22 Feb 2021 16:58:46 |
| User entered 'Nephrolithiasis' | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered '21 Feb 2021' | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered empty. | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Feb 2021 16:58:22 |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| | | |
| DataPoint Un-verified. | (b) (4), (b) (6) | 17 Mar 2021 14:58:16 |
| | | |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 17 Mar 2021 14:58:16 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| | | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 17 Mar 2021 14:58:16 |
| User entered '16 Mar 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 17 Mar 2021 14:58:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered empty. | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 18 Mar 2021 14:08:22 |
| Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'no end time reported by patient ' (Site from Safety). | (b) (4), (b) (6) | 17 Mar 2021 15:33:10 |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | (b) (4), (b) (6) | 03 Mar 2021 20:05:33 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered empty. | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Feb 2021 16:58:22 |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Severity](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System | 22 Feb 2021 16:59:04 |
| User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System | 22 Feb 2021 16:58:22 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered '0' | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered '0' | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---|--------------------------------------|--|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| 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). DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Mar 2021 09:51:06 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Patient is still hospitalized so no discharge data received ' (Site from System). User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). | (b) (4), (b) (6) (b) (4), (b) (6) | 25 Feb 2021 15:17:12 22 Feb 2021 16:59:09 |
| Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System). 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 | 22 Feb 2021 16:59:04 22 Feb 2021 16:59:04 |
| User entered '1' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Feb 2021 16:59:04 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). User entered '0' | System (b) (4), (b) (6) | 22 Feb 2021 16:58:22 22 Feb 2021 16:58:22 |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered '21 Feb 2021' | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 17 Mar 2021 14:58:16 |
| User entered '25 Feb 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 17 Mar 2021 14:58:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered empty. | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered empty. | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered '0' | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered '0' | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered '0' | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered '0' | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered 'I' | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered 'I' | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Outcome](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety). | (b) (4), (b) (6) | 18 Mar 2021 14:08:27 |
| Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'resolved' (Site from Safety). | (b) (4), (b) (6) | 17 Mar 2021 15:33:45 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 17 Mar 2021 14:58:16 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | (b) (4), (b) (6) | 17 Mar 2021 14:58:16 |
| User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety). | (b) (4), (b) (6) | 03 Mar 2021 20:05:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |
| User entered empty. | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Narrative](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User closed query 'PV Query: Please confirm the start/end dates of the patient's atrial fibrillation as it is listed twice with conflicting start/end dates. Were these 2 separate events?' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 29 Mar 2021 14:07:31 |
| Query 'PV Query: Please confirm the start/end dates of the patient's atrial fibrillation as it is listed twice with conflicting start/end dates. Were these 2 separate events?' answered with 'Please clarify since this SAE is not for A fib ' (Site from Safety). | (b) (4), (b) (6) | 25 Mar 2021 18:40:55 |
| User opened query 'PV Query: Please confirm the start/end dates of the patient's atrial fibrillation as it is listed twice with conflicting start/end dates. Were these 2 separate events?' (Site from Safety). | (b) (4), (b) (6) | 23 Mar 2021 12:18:02 |
| User closed query 'PV Query: Please confirm the start/end dates of the patient's skin cancer and atrial fibrillation, as they are each listed twice with both ongoing and historical dates.' (Site from Safety). | (b) (4), (b) (6) | 18 Mar 2021 14:08:30 |
| Query 'PV Query: Please confirm the start/end dates of the patient's skin cancer and atrial fibrillation, as they are each listed twice with both ongoing and historical dates.' answered with 'please clarify dates from this narrative ' (Site from Safety). | (b) (4), (b) (6) | 17 Mar 2021 15:33:38 |
| User opened query 'PV Query: Please confirm the start/end dates of the patient's skin cancer and atrial fibrillation, as they are each listed twice with both ongoing and historical dates.' (Site from Safety). | (b) (4), (b) (6) | 03 Mar 2021 20:03:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:17:12 |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Narrative](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered 'PATIENT WENT TO EMERGENCY ROOM ON 21 FEB 2021 FOR FATIGUE, CHILLS, ACHES, ABDOMINAL PAIN, NAUSEA, AND VOMITING. LAB STUDIES CAME BACK NEGATIVE FOR COVID-19 AND OVERALL WITHOUT FOCAL ABNORMALITY. EKG NORMAL, CT OF PELVIS SHOWS 8MM PROXIMAL RIGHT URETERAL STONE, URINALYSIS SHOWS SIGNIFICANT NITRITES, BLOOD, AND LEUKOCYTES. IV ROCEPHIN ADMINISTERED, BLOOD CULTURES DRAWN. CYSTOSCOPY WITH STENT PLACEMENT IN RIGHT URETER OCCURRED ON 22 FEB 2021.' | (b) (4), (b) (6) | 22 Feb 2021 16:58:22 |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 22 Feb 2021 16:58:22 |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 22 Feb 2021 16:58:22 |

US3762120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 22 Feb 2021 16:58:22 |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[AEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 18 Mar 2021 14:10:01 |
| User entered | (b) (4), (b) (6) | 18 Mar 2021 14:09:04 |
| 'USA-US130-2021-mRNA-1273-P301000005' | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Staphylococcal infections, PT: Staphylococcal bacteraemia, LLT: Staphylococcus aureus bacteremia - version MedDRA\\23.0. | Coder Import (b) (4) | 31 Mar 2021 08:43:27 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 31 Mar 2021 08:43:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| Data point term sent to Coder | System | 23 Mar 2021 15:13:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 23 Mar 2021 15:13:05 |
| Coding entries removed. | (b) (4), (b) (6) | 23 Mar 2021 15:13:05 |
| User entered 'METHICILLIN-SUSCEPTIBLE STAPHYLOCOCCUS AUREUS Bacteremia' reason for change: Data Entry Error | (b) (4), (b) (6) | 23 Mar 2021 15:13:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Staphylococcal infections, PT: Staphylococcal infection, LLT: Methicillin-resistant Staphylococcus aureus infection - version MedDRA\\23.0. | Coder Import (b) (4) | 17 Mar 2021 15:32:44 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 17 Mar 2021 15:32:44 |
| Data point term sent to Coder | System | 17 Mar 2021 15:32:33 |
| User entered 'methicillin-susceptible Staphylococcus aureus' | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered 'No (N)' | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered 'No (N)' | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered '13 Mar 2021' | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered empty. | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 17 Mar 2021 15:31:53 |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Apr 2021 13:41:39 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 29 Mar 2021 18:51:53 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 29 Mar 2021 18:51:53 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Apr 2021 13:41:39 |
| User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety). | (b) (4), (b) (6) | 30 Mar 2021 11:50:14 |
| Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' answered with 'end date updated' (Site from Safety). | (b) (4), (b) (6) | 29 Mar 2021 18:52:05 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 29 Mar 2021 18:51:53 |
| User entered '17 Mar 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 29 Mar 2021 18:51:53 |
| User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety). | (b) (4), (b) (6) | 23 Mar 2021 12:17:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered empty. | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered empty. | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 17 Mar 2021 15:31:53 |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Severity](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered '0' | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered '0' | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | (b) (4), (b) (6) | 18 Apr 2021 11:45:27 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'all information is entered' (Site from System). | Samantha Wheeler (b) (4) | 08 Apr 2021 21:36:51 |
| 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 | 08 Apr 2021 21:35:38 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | (b) (4), (b) (6) | 31 Mar 2021 13:52:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'no discharge date is recorded' (Site from System). | (b) (4), (b) (6) | 17 Mar 2021 15:32:43 |
| 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 | 17 Mar 2021 15:31:53 |
| User entered 'I' | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:16:26 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Un-verified. | Samantha Wheeler (b) (4) | 08 Apr 2021 21:35:38 |
| User entered '14 Mar 2021' reason for change: Data Entry Error | Samantha Wheeler (b) (4) | 08 Apr 2021 21:35:38 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered '13 Mar 2021' | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety). | (b) (4), (b) (6) | 24 Mar 2021 14:56:12 |
| Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety). | (b) (4), (b) (6) | 23 Mar 2021 15:13:34 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 23 Mar 2021 15:13:05 |
| User entered '17 Mar 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 23 Mar 2021 15:13:05 |
| User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety). | (b) (4), (b) (6) | 23 Mar 2021 12:18:19 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered empty. | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 17 Mar 2021 15:32:25 |
| User entered 'No (N)' | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered empty. | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered '0' | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered '0' | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered '0' | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered '0' | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 24 Mar 2021 14:56:18 |
| Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Con meds updated' (Site from Safety). | (b) (4), (b) (6) | 23 Mar 2021 15:13:41 |
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6) | 23 Mar 2021 12:19:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered 'I' | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered '0' | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Outcome](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Apr 2021 13:41:39 |
| User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety). | (b) (4), (b) (6) | 30 Mar 2021 11:50:29 |
| Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'updated as recovered' (Site from Safety). | (b) (4), (b) (6) | 29 Mar 2021 18:52:17 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 29 Mar 2021 18:51:53 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | (b) (4), (b) (6) | 29 Mar 2021 18:51:53 |
| User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety). | (b) (4), (b) (6) | 23 Mar 2021 12:17:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:41:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered empty. | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Narrative](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User closed query 'PV Query: Please confirm hospital admission date as it is reported as both 13 Mar 2021 and 14 Mar 2021. Please correct.' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 09 Apr 2021 12:17:53 |
| Query 'PV Query: Please confirm hospital admission date as it is reported as both 13 Mar 2021 and 14 Mar 2021. Please correct.' answered with 'updated' (Site from Safety). | Samantha Wheeler (b) (4) (b) (4) | 08 Apr 2021 21:35:45 |
| User opened query 'PV Query: Please confirm hospital admission date as it is reported as both 13 Mar 2021 and 14 Mar 2021. Please correct.' (Site from Safety). | (b) (4), (b) (6) | 02 Apr 2021 01:47:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User closed query 'PV Query: It was reported that this was a case of reoccurring MRSA, however, the subject has no medical history of MRSA. Please add previous MRSA infections to the subjects medical history.' (Site from Safety). | (b) (4), (b) (6) | 24 Mar 2021 22:35:48 |
| Query 'PV Query: It was reported that this was a case of reoccurring MRSA, however, the subject has no medical history of MRSA. Please add previous MRSA infections to the subjects medical history.' answered with 'previous MSSA reported to AE log ' (Site from Safety). | (b) (4), (b) (6) | 24 Mar 2021 19:06:26 |
| 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) | 24 Mar 2021 14:56:25 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). | (b) (4), (b) (6) | 24 Mar 2021 14:56:22 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Narrative](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'covid test result provided as negative' (Site from Safety). | (b) (4), (b) (6) | 23 Mar 2021 15:15:36 |
| User entered 'PATIENT IS A 79-YEAR-OLD MALE WHO PRESENTED WITH FEVER AT HOME. PATIENT REPORTED THAT HIS TEMPERATURE WAS NORMAL THAT MORNING, BUT THAT EVENING HE FELT WARM AND WITH CHILLS. HE CHECKED HIS TEMPERATURE ORALLY AND IT WAS MEASURED AT ABOUT 102 AT HOME. PATIENT ALSO REPORTED THAT HE HAD RIGHT FLANK PAIN AND TROUBLE INITIATING URINATION BECAUSE OF THE STENT, HOWEVER, THIS IS NOT NEW AND HAS BEEN EXPERIENCING THIS FOR A WHILE. IT WAS DISCOVERED PATIENT HAD A REOCCURRING INCIDENT OF METHICILLIN-SUSCEPTIBLE STAPHYLOCOCCUS AUREUS. ADMITTED ON 3/14 FOR FEVER AND CHILLS, FOUND TO HAVE E. COLI UTI IN SETTING OF RECENT URETERAL STENT PLACEMENT. HE RECEIVED IV ANTIBIOTICS AND WAS FOLLOWED CLOSELY BY ID AND UROLOGY. HAD A STENT REMOVAL, STONES BLASTED, NEW STENT PLACE. Covid-19 test was performed on 3/14/2021 and resulted as negative for COVid-19. SIGNIFICANT DIAGNOSTIC LABS INCLUDE CBC; 3/14/2021 WBC 11.0, HGB 10.8, HCT 31.0, 3/15/2021 WBC 7.8, HGB 10.4, HCT 30.6, 3/16/2021 WBC 3.5, HGT 10.9, HCT 31.7, 3/17/2021 WBC 7.6, HGB 11.2, HCT 32.3. DISCHARGED ON 3/17/2021 AWAITING AN UPDATE AFTER VISIT WITH PCP AFTER APRIL 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 23 Mar 2021 15:15:23 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[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. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'All labs documented in narrative ' (Site from Safety). DataPoint Un-verified. | (b) (4), (b) (6) | 23 Mar 2021 15:14:25 |
| | (b) (4), (b) (6) | 23 Mar 2021 15:13:05 |
| User entered 'PATIENT IS A 79-YEAR-OLD MALE WHO PRESENTED WITH FEVER AT HOME. PATIENT REPORTED THAT HIS TEMPERATURE WAS NORMAL THAT MORNING, BUT THAT EVENING HE FELT WARM AND WITH CHILLS. HE CHECKED HIS TEMPERATURE ORALLY AND IT WAS MEASURED AT ABOUT 102 AT HOME. PATIENT ALSO REPORTED THAT HE HAD RIGHT FLANK PAIN AND TROUBLE INITIATING URINATION BECAUSE OF THE STENT, HOWEVER, THIS IS NOT NEW AND HAS BEEN EXPERIENCING THIS FOR A WHILE. IT WAS DISCOVERED PATIENT HAD A REOCCURRING INCIDENT OF METHICILLIN-SUSCEPTIBLE STAPHYLOCOCCUS AUREUS. Admitted on 3/14 for fever and chills, found to have E. Coli Uti in setting of recent ureteral stent placement. He received IV antibiotics and was followed closely by ID and Urology. Had a stent removal, stones blasted, new stent place. Significant diagnostic labs include CBC; 3/14/2021 WBC 11.0, HGB 10.8, HCT 31.0, 3/15/2021 WBC 7.8, HGB 10.4, HCT 30.6, 3/16/2021 WBC 3.5, HGT 10.9, HCT 31.7, 3/17/2021 WBC 7.6, HGB 11.2, HCT 32.3. Discharged on 3/17/2021 awaiting an update after visit with PCP after April 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 23 Mar 2021 15:13:05 |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Narrative](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User opened query 'PV Query: It was reported that this was a case of reoccurring MRSA, however, the subject has no medical history of MRSA. Please add previous MRSA infections to the subjects medical history.' (Site from Safety). | (b) (4), (b) (6) | 23 Mar 2021 12:18:53 |
| 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) | 23 Mar 2021 12:18:44 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). | (b) (4), (b) (6) | 23 Mar 2021 12:18:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Mar 2021 15:27:08 |
| User entered 'Patient is a 79-year-old male who presented with fever at home. Patient reported that his temperature was normal that morning, but that evening he felt warm and with chills. He checked his temperature orally and it was measured at about 102 at home. Patient also reported that he had right flank pain and trouble initiating urination because of the stent, however, this is not new and has been experiencing this for a while. It was discovered patient had a reoccurring incident of methicillin-susceptible Staphylococcus aureus.' | (b) (4), (b) (6) | 17 Mar 2021 15:31:53 |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 17 Mar 2021 15:31:53 |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 17 Mar 2021 15:31:53 |

US3762120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 17 Mar 2021 15:31:53 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[AEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Mar 2021 20:21:34 |
| User entered | (b) (4), (b) (6) | 24 Mar 2021 20:21:28 |
| 'USA-US130-2021-mRNA-1273-P301000005' | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Escherichia infections, PT: Escherichia urinary tract infection, LLT: Escherichia urinary tract infection - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 24 Mar 2021 10:21:39 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 24 Mar 2021 10:21:39 |
| Data point term sent to Coder | System | 23 Mar 2021 15:32:46 |
| User entered 'E. Coli UTI' | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'No (N)' | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'No (N)' | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '14 Mar 2021' | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered empty. | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Apr 2021 13:41:39 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 29 Mar 2021 18:52:52 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 29 Mar 2021 18:52:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 25 Mar 2021 18:25:41 |
| User entered 'No (N)' | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Apr 2021 13:41:39 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 29 Mar 2021 18:52:52 |
| User entered '29 Mar 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 29 Mar 2021 18:52:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System). | System | 25 Mar 2021 18:25:41 |
| User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System). | System | 23 Mar 2021 15:31:47 |
| User entered empty. | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | 25 Mar 2021 19:02:24 |
| User entered empty. | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Severity](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User closed query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible.' (Site from Safety). | (b) (4), (b) (6) | 24 Mar 2021 20:21:03 |
| Query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible.' answered with 'updated info' (Site from Safety). | (b) (4), (b) (6) | 24 Mar 2021 19:07:49 |
| User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System | 24 Mar 2021 19:07:27 |
| User opened query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible.' (Site from Safety). | (b) (4), (b) (6) | 24 Mar 2021 02:12:25 |
| User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System | 23 Mar 2021 15:31:47 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '0' | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '0' | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 13:51:39 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'updated info ' (Site from System). | (b) (4), (b) (6) | 24 Mar 2021 19:07:43 |
| User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). | | 24 Mar 2021 19:07:27 |
| Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System). | | 24 Mar 2021 19:07:27 |
| 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 | 24 Mar 2021 19:07:27 |
| User entered '1' reason for change: Data Entry Error | (b) (4), (b) (6) | 24 Mar 2021 19:07:27 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). | System | 23 Mar 2021 15:31:47 |
| User entered '0' | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '14 Mar 2021' | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '17 Mar 2021' | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered empty. | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered empty. | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '0' | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '0' | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '0' | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '0' | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'I' | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '0' | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Outcome](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Apr 2021 13:41:39 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 29 Mar 2021 18:52:52 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: | (b) (4), (b) (6) | 29 Mar 2021 18:52:52 |
| Data Entry Error | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered empty. | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Narrative](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User closed query 'PV Query: Please confirm hospital admission date as it is reported as both 13 Mar 2021 and 14 Mar 2021. Please correct.' (Site from Safety). | (b) (4) | |
| Query 'PV Query: Please confirm hospital admission date as it is reported as both 13 Mar 2021 and 14 Mar 2021. Please correct.' answered with 'admitted on 3/14/21' (Site from Safety). | (b) (4), (b) (6) | 09 Apr 2021 12:18:08 |
| User opened query 'PV Query: Please confirm hospital admission date as it is reported as both 13 Mar 2021 and 14 Mar 2021. Please correct.' (Site from Safety). | Samantha Wheeler (b) (4) | 08 Apr 2021 21:37:15 |
| DataPoint Verified. | (b) (4) | |
| User opened query 'PV Query: Please confirm hospital admission date as it is reported as both 13 Mar 2021 and 14 Mar 2021. Please correct.' (Site from Safety). | (b) (4), (b) (6) | 02 Apr 2021 01:46:49 |
| | | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User entered 'PATIENT IS A 79-YEAR-OLD MALE WHO PRESENTED WITH FEVER AT HOME. PATIENT REPORTED THAT HIS TEMPERATURE WAS NORMAL THAT MORNING, BUT THAT EVENING HE FELT WARM AND WITH CHILLS. HE CHECKED HIS TEMPERATURE ORALLY AND IT WAS MEASURED AT ABOUT 102 AT HOME. PATIENT ALSO REPORTED THAT HE HAD RIGHT FLANK PAIN AND TROUBLE INITIATING URINATION BECAUSE OF THE STENT, HOWEVER, THIS IS NOT NEW AND HAS BEEN EXPERIENCING THIS FOR A WHILE. IT WAS DISCOVERED PATIENT HAD A REOCCURRING INCIDENT OF METHICILLIN-SUSCEPTIBLE STAPHYLOCOCCUS AUREUS. Patient was found to have E. Coli UTI in setting of recent ureteral stent placement. Admitted on 3/14 for fever and chills, found to have E. Coli Uti in setting of recent ureteral stent placement. He received IV antibiotics and was followed closely by ID and Urology. Had a stent removal, stones blasted, new stent place. Significant diagnostic labs include CBC; 3/14/2021 WBC 11.0, HGB 10.8, HCT 31.0, 3/15/2021 WBC 7.8, HGB 10.4, HCT 30.6, 3/16/2021 WBC 3.5, HGT 10.9, HCT 31.7, 3/17/2021 WBC 7.6, HGB 11.2, HCT 32.3. Discharged on 3/17/2021 awaiting an update after visit with PCP after April 2021' | (b) (4), (b) (6) | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 23 Mar 2021 15:31:47 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[AEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Mar 2021 20:51:55 |
| User entered | (b) (4), (b) (6) | 24 Mar 2021 20:51:48 |
| 'USA-US130-2021-mRNA-1273-P301000005' | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Staphylococcal infections, PT: Staphylococcal bacteraemia, LLT: Staphylococcus aureus bacteremia - version MedDRA\\23.0. | Coder Import (b) (4) | 31 Mar 2021 08:43:27 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 31 Mar 2021 08:43:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| Data point term sent to Coder | System | 23 Mar 2021 15:45:22 |
| User entered 'METHICILLIN-SUSCEPTIBLE STAPHYLOCOCCUS AUREUS BACTEREMIA' | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'No (N)' | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | 25 Mar 2021 19:02:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '21 Feb 2021' | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered empty. | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'No (N)' | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '25 Feb 2021' | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | 25 Mar 2021 19:02:24 |
| User entered empty. | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Severity](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User closed query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible.' (Site from Safety). | (b) (4), (b) (6) | 24 Mar 2021 22:36:03 |
| Query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible.' answered with 'updated required hospitalization' (Site from Safety). | (b) (4), (b) (6) | 24 Mar 2021 21:20:28 |
| User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System | 24 Mar 2021 21:19:23 |
| User opened query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible.' (Site from Safety). | (b) (4), (b) (6) | 24 Mar 2021 02:12:50 |
| User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System | 23 Mar 2021 15:44:30 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '0' | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '0' | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| 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). DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 13:51:58 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'updated with hospitalization stay ' (Site from System). | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). | (b) (4), (b) (6) | 24 Mar 2021 21:20:38 |
| Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System). | | 24 Mar 2021 21:19:23 |
| 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 | 24 Mar 2021 21:19:23 |
| User entered '1' reason for change: Data Entry Error | (b) (4), (b) (6) | 24 Mar 2021 21:19:23 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). | System | 23 Mar 2021 15:44:30 |
| User entered '0' | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | 25 Mar 2021 19:02:24 |
| User entered '21 Feb 2021' | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '25 Feb 2021' | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | 25 Mar 2021 19:02:24 |
| User entered empty. | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered empty. | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '0' | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '0' | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '0' | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[None](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:16:26 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Un-verified. | (b) (4) | |
| | Samantha Wheeler (b) (4) | 08 Apr 2021 13:09:41 |
| User entered '0' reason for change: Data Entry Error | (b) (4) | |
| | Samantha Wheeler (b) (4) | 08 Apr 2021 13:09:41 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '1' | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:16:26 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Un-verified. | (b) (4) | |
| | Samantha Wheeler (b) (4) | 08 Apr 2021 13:09:41 |
| User entered '1' reason for change: Data Entry Error | (b) (4) | |
| | Samantha Wheeler (b) (4) | 08 Apr 2021 13:09:41 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '0' | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '0' | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Outcome](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered empty. | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Narrative](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User closed query 'Per DM CLR: SAE Narrative= R URETERAL STONE WITH HYDROURETERONEPHROSIS AND STRANDING. Review if this should be recorded as a separate AE. Else, clarify. ' (Site from DM). | (b) (4), (b) (6) | 26 Apr 2021 10:19:32 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| Query 'Per DM CLR: SAE Narrative= R URETERAL STONE WITH HYDROURETERONEPHROSIS AND STRANDING. Review if this should be recorded as a separate AE. Else, clarify. ' answered with 'no- this is related to the nephrolithiasis.' (Site from DM). | Samantha Wheeler (b) (4) | 08 Apr 2021 21:38:04 |
| User opened query 'Per DM CLR: SAE Narrative= R URETERAL STONE WITH HYDROURETERONEPHROSIS AND STRANDING. Review if this should be recorded as a separate AE. Else, clarify. ' (Site from DM). | (b) (4), (b) (6) | 06 Apr 2021 07:14:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '79 y.o. male w/ hx Afib (on eliquis) and nephrolithiasis with 8mm proximal R ureteral stone with hydroureteronephrosis and stranding. Febrile to 102.5 at OSH, no leukocytosis, tachycardic, hypotensive. He was taken to the OR E2 for a right ureteral stent placement. ID was consulted postoperatively for bacteremia due to MSSA.' | (b) (4), (b) (6) | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 23 Mar 2021 15:44:30 |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[AEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Mar 2021 22:43:10 |
| User entered | (b) (4), (b) (6) | 24 Mar 2021 22:43:01 |
| 'USA-US130-2021-mRNA-1273-P301000005' | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Complicated urinary tract infection - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 24 Mar 2021 21:23:44 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 24 Mar 2021 21:23:44 |
| Data point term sent to Coder | System | 24 Mar 2021 21:23:13 |
| User entered 'Complicated Urinary Tract Infection' | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'No (N)' | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 24 Mar 2021 21:23:33 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 24 Mar 2021 21:23:33 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 24 Mar 2021 21:23:33 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 24 Mar 2021 21:23:08 |
| User entered empty. | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '21 Feb 2021' | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered empty. | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Mar 2021 21:23:08 |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'No (N)' | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '25 Feb 2021' | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | 25 Mar 2021 19:02:24 |
| User entered empty. | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Mar 2021 21:23:08 |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[Severity](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System | 24 Mar 2021 21:23:33 |
| User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System | 24 Mar 2021 21:23:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '0' | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '0' | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 13:52:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'updated with hospitalization ' (Site from System). | (b) (4), (b) (6) | 24 Mar 2021 21:23:46 |
| User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). | | 24 Mar 2021 21:23:33 |
| Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System). | | 24 Mar 2021 21:23:33 |
| 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 | 24 Mar 2021 21:23:33 |
| User entered '1' reason for change: Data Entry Error | (b) (4), (b) (6) | 24 Mar 2021 21:23:33 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). | System | 24 Mar 2021 21:23:08 |
| User entered '0' | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '21 Feb 2021' | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '25 Feb 2021' | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered empty. | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered empty. | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '0' | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '0' | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '0' | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '0' | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'I' | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered '0' | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[Outcome](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered empty. | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |
| | | |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[Narrative](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Mar 2021 19:02:24 |
| User entered 'PATIENT WENT TO EMERGENCY ROOM ON 21 FEB 2021 FOR FATIGUE, CHILLS, ACHES, ABDOMINAL PAIN, NAUSEA, AND VOMITING. LAB STUDIES CAME BACK NEGATIVE FOR COVID-19 AND OVERALL WITHOUT FOCAL ABNORMALITY. EKG NORMAL, CT OF PELVIS SHOWS 8MM PROXIMAL RIGHT URETERAL STONE, URINALYSIS SHOWS SIGNIFICANT NITRITES, BLOOD, AND LEUKOCYTES. IV ROCEPHIN ADMINISTERED, BLOOD CULTURES DRAWN. CYSTOSCOPY WITH STENT PLACEMENT IN RIGHT URETER OCCURRED ON 22 FEB 2021.' | (b) (4), (b) (6) | 24 Mar 2021 21:23:08 |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 24 Mar 2021 21:23:08 |

US3762120

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:41:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 24 Mar 2021 21:23:08 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:41:43

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 05:37:03 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:17:27 |
| User entered 'Yes (Y)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:41:10 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:43

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| 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) (b) (4) | 06 Sep 2020 09:23:49 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 06 Sep 2020 09:23:49 |
| Data point term sent to Coder | System | 03 Sep 2020 18:43:07 |
| User entered 'Metoprolol' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:42:38 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:43

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Yes (Y)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:42:38 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:43

[Indication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Thoracic Aneurism Prophylaxis' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:42:38 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:43

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered '25' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:42:38 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:43

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'mg (mg)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:42:38 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:43

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:42:38 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:43

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'once daily (QD)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:42:38 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:43

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:42:38 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:43

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Oral (ORAL)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:42:38 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:43

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:42:38 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered '01 Jan 2000' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:42:38 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered '0' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:42:38 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:43

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Yes (Y)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:42:38 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:43

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:42:38 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:43

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'No (N)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:42:38 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:43

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Sep 2020 18:42:38 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Sep 2020 18:42:38 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 03 Sep 2020 18:42:38 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:43

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 05 Sep 2020 12:22:45 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 05 Sep 2020 12:22:45 |
| Data point term sent to Coder | System | 03 Sep 2020 18:44:10 |
| User entered 'Losartan' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:43:40 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:43

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Yes (Y)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:43:40 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:43

[Indication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Thoracic Aneurism Prophylaxis' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:43:40 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:43

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered '100' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:43:40 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:43

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'mg (mg)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:43:40 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:43

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:43:40 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:43

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'once daily (QD)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:43:40 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:43

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:43:40 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:43

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Oral (ORAL)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:43:40 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:43

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:43:40 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered '01 Jan 2000' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:43:40 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered '0' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:43:40 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:43

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Yes (Y)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:43:40 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:43

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:43:40 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:43

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'No (N)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:43:40 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:43

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Sep 2020 18:43:40 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Sep 2020 18:43:40 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 03 Sep 2020 18:43:40 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:43

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 03 Sep 2020 18:45:46 |
| | (b) (4) | |
| User coded data point as Term Coded data point by | Coder Import (b) (4) | 03 Sep 2020 18:45:46 |
| User: Coder System - version | (b) (4) | |
| WHODrug-Global-B3\\202003. | | |
| Data point term sent to Coder | System | 03 Sep 2020 18:45:12 |
| User entered 'Atorvastatin' | James Lovette (b) (4) | 03 Sep 2020 18:44:44 |
| | (b) (4) | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:43

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Yes (Y)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:44:44 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:43

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Cholesterol Management' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:44:44 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:43

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered '10' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:44:44 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:43

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'mg (mg)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:44:44 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:43

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:44:44 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:43

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'once daily (QD)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:44:44 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:43

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:44:44 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:43

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Oral (ORAL)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:44:44 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:43

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:44:44 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered '01 Jan 1995' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:44:44 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered '0' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:44:44 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:43

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Yes (Y)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:44:44 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:43

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:44:44 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:43

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'No (N)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:44:44 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:43

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Sep 2020 18:44:44 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Sep 2020 18:44:44 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 03 Sep 2020 18:44:44 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:43

Name of Medication

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 04 Sep 2020 06:02:36 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 04 Sep 2020 06:02:36 |
| Data point term sent to Coder | System | 03 Sep 2020 18:46:14 |
| User entered 'Apixiban' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:46:12 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:43

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Yes (Y)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:46:12 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:43

[Indication](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM). | (b) (4), (b) (6) | 09 Oct 2020 14:57:11 |
| Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'added' (Site from DM). | Samantha Wheeler (b) (4) (b) (4) | 06 Oct 2020 19:21:59 |
| User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM). | (b) (4), (b) (6) | 06 Oct 2020 02:44:43 |
| User entered 'Paroxysmal Atrial Fibrillation' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:46:12 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:43

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered '5' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:46:12 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:43

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'mg (mg)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:46:12 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:43

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:46:12 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:43

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'twice daily (BID)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:46:12 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:43

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:46:12 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:43

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Oral (ORAL)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:46:12 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:43

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:46:12 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered '01 Jan 2019' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:46:12 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered '0' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:46:12 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:43

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Yes (Y)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:46:12 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:43

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:46:12 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:43

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'No (N)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:46:12 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:43

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 03 Sep 2020 18:46:12 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Sep 2020 18:46:12 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 03 Sep 2020 18:46:12 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:43

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TERAZOSIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 03 Sep 2020 18:48:24 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 03 Sep 2020 18:48:24 |
| Data point term sent to Coder | System | 03 Sep 2020 18:47:19 |
| User entered 'Terazosin' | James Lovette (b) (4) | 03 Sep 2020 18:47:07 |
| | (b) (4) | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:43

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Yes (Y)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:43

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'BPH' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:43

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered '10' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:43

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'mg (mg)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:43

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:43

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'once daily (QD)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:43

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:43

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Oral (ORAL)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:43

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered '01 Jan 2016' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered '0' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:43

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Yes (Y)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:43

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:43

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'No (N)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:43

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Sep 2020 18:47:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Sep 2020 18:47:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 03 Sep 2020 18:47:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:43

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: OTHER DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, PRODUCT: TADALAFIL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 03 Sep 2020 18:48:43 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 03 Sep 2020 18:48:43 |
| Data point term sent to Coder | System | 03 Sep 2020 18:48:20 |
| User entered 'Tadalafil' | James Lovette (b) (4) | 03 Sep 2020 18:47:51 |
| | (b) (4) | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:43

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Yes (Y)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:51 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:43

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'BPH' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:51 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:43

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered '5' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:51 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:43

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'mg (mg)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:51 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:43

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:51 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:43

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'once daily (QD)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:51 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:43

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:51 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:43

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Oral (ORAL)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:51 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:43

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:51 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered '01 Jan 2016' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:51 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered '0' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:51 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:43

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Yes (Y)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:51 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:43

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:51 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:43

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'No (N)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:47:51 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:43

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Sep 2020 18:47:51 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Sep 2020 18:47:51 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 03 Sep 2020 18:47:51 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:43

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 03 Sep 2020 18:50:58 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 03 Sep 2020 18:50:58 |
| Data point term sent to Coder | System | 03 Sep 2020 18:49:24 |
| User entered 'Vitamin D' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:48:50 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:43

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Yes (Y)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:48:50 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:43

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'prevention' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:48:50 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:43

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered '25' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:48:50 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:43

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User closed query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 08 Oct 2020 12:58:53 |
| Query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' answered with 'updated' (Site from DM). | Samantha Wheeler (b) (4) | 06 Oct 2020 19:23:27 |
| | (b) (4) | |
| User entered 'ug (ug)' reason for change: Data Entry Error | Samantha Wheeler (b) (4) | 06 Oct 2020 19:23:20 |
| | (b) (4) | |
| User opened query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 05 Oct 2020 17:52:23 |
| | | |
| User entered 'Other (OTHER)' | James Lovette (b) (4) | 03 Sep 2020 18:48:50 |
| | (b) (4) | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:43

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty; reason for change Data Entry Error | Samantha Wheeler (b) (4) (b) (4) | 06 Oct 2020 19:23:20 |
| User entered 'mcg' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:48:50 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:43

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'once daily (QD)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:48:50 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:43

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:48:50 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:43

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Oral (ORAL)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:48:50 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:43

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:48:50 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered '01 Jan 2016' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:48:50 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered '0' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:48:50 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:43

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Yes (Y)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:48:50 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:43

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:48:50 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:43

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'No (N)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:48:50 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:43

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Sep 2020 18:48:50 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Sep 2020 18:48:50 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 03 Sep 2020 18:48:50 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:43

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 04 Sep 2020 16:05:46 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 04 Sep 2020 16:05:46 |
| Data point term sent to Coder | System | 03 Sep 2020 18:50:28 |
| User entered 'Vitamin B12' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:49:55 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:43

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Yes (Y)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:49:55 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:43

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'prevention' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:49:55 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:43

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered '1000' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:49:55 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:43

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User closed query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 08 Oct 2020 12:59:22 |
| Query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' answered with 'updated' (Site from DM). | Samantha Wheeler (b) (4) | 06 Oct 2020 19:23:46 |
| | (b) (4) | |
| User entered 'ug (ug)' reason for change: Data Entry Error | Samantha Wheeler (b) (4) | 06 Oct 2020 19:23:42 |
| | (b) (4) | |
| User opened query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 05 Oct 2020 17:52:30 |
| | | |
| User entered 'Other (OTHER)' | James Lovette (b) (4) | 03 Sep 2020 18:49:55 |
| | (b) (4) | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:43

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty; reason for change Data Entry Error | Samantha Wheeler (b) (4) (b) (4) | 06 Oct 2020 19:23:42 |
| User entered 'mcg' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:49:55 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:43

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'once daily (QD)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:49:55 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:43

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:49:55 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:43

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Oral (ORAL)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:49:55 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:43

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:49:55 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered '01 Jan 2016' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:49:55 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered '0' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:49:55 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:43

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'Yes (Y)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:49:55 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:43

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered empty. | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:49:55 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:43

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| User entered 'No (N)' | James Lovette (b) (4) (b) (4) | 03 Sep 2020 18:49:55 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:43

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Sep 2020 18:49:55 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Sep 2020 18:49:55 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 03 Sep 2020 18:49:55 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:43

Name of Medication

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:53 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Mar 2021 07:41:40 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Mar 2021 07:41:40 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| Data point term sent to Coder | System | 22 Feb 2021 17:01:50 |
| User entered 'Rocephin' | (b) (4), (b) (6) | 22 Feb 2021 17:01:13 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:43

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:53 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Feb 2021 17:01:13 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:43

[Indication](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:53 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered 'nephrolithiasis' | (b) (4), (b) (6) | 22 Feb 2021 17:01:13 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:43

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:53 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered '1' | (b) (4), (b) (6) | 22 Feb 2021 17:01:13 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:43

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:53 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered 'g (g)' | (b) (4), (b) (6) | 22 Feb 2021 17:01:13 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:43

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:53 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered empty. | (b) (4), (b) (6) | 22 Feb 2021 17:01:13 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:43

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:53 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 22 Feb 2021 17:01:13 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:43

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:53 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered empty. | (b) (4), (b) (6) | 22 Feb 2021 17:01:13 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:43

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:53 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered 'Intravenous (INTRAVENOUS)' | (b) (4), (b) (6) | 22 Feb 2021 17:01:13 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:43

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:53 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered empty. | (b) (4), (b) (6) | 22 Feb 2021 17:01:13 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:53 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered '21 Feb 2021' | (b) (4), (b) (6) | 22 Feb 2021 17:01:13 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:53 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered '0' | (b) (4), (b) (6) | 22 Feb 2021 17:01:13 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:43

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:53 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Un-verified. | (b) (4), (b) (6) | 26 Mar 2021 14:58:40 |
| | | |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 26 Mar 2021 14:58:40 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Feb 2021 17:01:13 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:43

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:53 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Un-verified. | (b) (4), (b) (6) | 26 Mar 2021 14:58:40 |
| | | |
| User entered '21 Feb 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 26 Mar 2021 14:58:40 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered empty. | (b) (4), (b) (6) | 22 Feb 2021 17:01:13 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:43

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:53 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Feb 2021 17:01:13 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:43

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:53 |
| | | |
| User entered '1' | System | 22 Feb 2021 17:01:13 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:53 |
| | | |
| User entered '1' | System | 22 Feb 2021 17:01:13 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:53 |
| | | |
| User entered '804 (804)' | System | 22 Feb 2021 17:01:13 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:43

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:57 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 22 Feb 2021 17:03:59 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 22 Feb 2021 17:03:59 |
| | (b) (4) | |
| Data point term sent to Coder | System | 22 Feb 2021 17:02:51 |
| User entered 'Acetaminophen' | (b) (4), (b) (6) | 22 Feb 2021 17:02:07 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:43

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:57 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Feb 2021 17:02:07 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:43

[Indication](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:57 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered 'nephrolithiasis' | (b) (4), (b) (6) | 22 Feb 2021 17:02:07 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:43

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:57 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered '1000' | (b) (4), (b) (6) | 22 Feb 2021 17:02:07 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:43

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:57 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 22 Feb 2021 17:02:07 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:43

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:57 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered empty. | (b) (4), (b) (6) | 22 Feb 2021 17:02:07 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:43

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:57 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered 'as needed (PRN)' | (b) (4), (b) (6) | 22 Feb 2021 17:02:07 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:43

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:57 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered empty. | (b) (4), (b) (6) | 22 Feb 2021 17:02:07 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:43

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:57 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 22 Feb 2021 17:02:07 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:43

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:57 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered empty. | (b) (4), (b) (6) | 22 Feb 2021 17:02:07 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:43

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:57 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered '21 Feb 2021' | (b) (4), (b) (6) | 22 Feb 2021 17:02:07 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:57 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered '0' | (b) (4), (b) (6) | 22 Feb 2021 17:02:07 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:43

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:57 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Un-verified. | (b) (4), (b) (6) | 26 Mar 2021 14:59:00 |
| | | |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 26 Mar 2021 14:59:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Feb 2021 17:02:07 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:43

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:57 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Un-verified. | (b) (4), (b) (6) | 26 Mar 2021 14:59:00 |
| | | |
| User entered '22 Feb 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 26 Mar 2021 14:59:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered empty. | (b) (4), (b) (6) | 22 Feb 2021 17:02:07 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:43

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:57 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:18:42 |
| | | |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Feb 2021 17:02:07 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:43

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:57 |
| | | |
| User entered empty. | System | 22 Feb 2021 17:02:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:57 |
| | | |
| User entered empty. | System | 22 Feb 2021 17:02:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:33:57 |
| | | |
| User entered empty. | System | 22 Feb 2021 17:02:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:43

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:07 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: OTHER ANTIBACTERIALS, PRODUCT: DAPTOMYCIN - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 30 Mar 2021 12:33:35 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 30 Mar 2021 12:33:35 |
| | (b) (4) | |
| Data point term sent to Coder | System | 26 Mar 2021 15:00:26 |
| User entered 'Daptomycin' | (b) (4), (b) (6) | 26 Mar 2021 15:00:08 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:43

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:07 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| User entered 'No (N)' | (b) (4), (b) (6) | 26 Mar 2021 15:00:08 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:43

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User closed query 'Per DM CLR: The corresponding recorded AE #4 does not show 'ConMed Administered' for Action Taken. Please update Action Taken for AE as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 15 Apr 2021 15:04:20 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| Query 'Per DM CLR: The corresponding recorded AE #4 does not show 'ConMed Administered' for Action Taken. Please update Action Taken for AE as appropriate. ' answered with 'updted' (Site from DM). | Samantha Wheeler (b) (4) | 08 Apr 2021 13:10:29 |
| User opened query 'Per DM CLR: The corresponding recorded AE #4 does not show 'ConMed Administered' for Action Taken. Please update Action Taken for AE as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 07 Apr 2021 08:10:36 |
| User entered 'MSSA Bacteremia' | (b) (4), (b) (6) | 26 Mar 2021 15:00:08 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:43

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '625' | (b) (4), (b) (6) | 26 Mar 2021 15:00:08 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:43

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 26 Mar 2021 15:00:08 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:43

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:07 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 26 Mar 2021 15:00:08 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:43

[Frequency](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:07 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| User entered 'other (OTHER)' | (b) (4), (b) (6) | 26 Mar 2021 15:00:08 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:43

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:07 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| User entered 'Q24' | (b) (4), (b) (6) | 26 Mar 2021 15:00:08 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:43

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'Intravenous (INTRAVENOUS)' | (b) (4), (b) (6) | 26 Mar 2021 15:00:08 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:43

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4), (b) (6) | 26 Mar 2021 15:00:08 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:43

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '25 Feb 2021' | (b) (4), (b) (6) | 26 Mar 2021 15:00:08 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '0' | (b) (4), (b) (6) | 26 Mar 2021 15:00:08 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:43

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'No (N)' | (b) (4), (b) (6) | 26 Mar 2021 15:00:08 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:43

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:07 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| User entered '28 Feb 2021' | (b) (4), (b) (6) | 26 Mar 2021 15:00:08 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:43

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'No (N)' | (b) (4), (b) (6) | 26 Mar 2021 15:00:08 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:43

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:07 |
| | | |
| User entered empty. | System | 26 Mar 2021 15:00:08 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:07 |
| | | |
| User entered empty. | System | 26 Mar 2021 15:00:08 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:07 |
| | | |
| User entered empty. | System | 26 Mar 2021 15:00:08 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:43

Name of Medication

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM DS - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Mar 2021 15:02:24 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Mar 2021 15:02:24 |
| Data point term sent to Coder | System | 26 Mar 2021 15:02:17 |
| User entered 'Bactrim DS' | (b) (4), (b) (6) | 26 Mar 2021 15:00:52 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:43

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 15:00:52 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:43

[Indication](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'E. Coli UTI' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 15:00:52 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:43

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '800-160' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 15:00:52 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:43

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 15:00:52 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:43

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 15:00:52 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:43

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'twice daily (BID)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 15:00:52 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:43

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 15:00:52 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:43

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 15:00:52 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:43

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 15:00:52 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '25 Feb 2021' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 15:00:52 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 15:00:52 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:43

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 29 Mar 2021 18:54:23 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 26 Mar 2021 15:00:52 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:43

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '27 Mar 2021' reason for change: Data Entry Error | (b) (4) | 29 Mar 2021 18:54:23 |
| User entered empty. | (b) (4), (b) (6) | 26 Mar 2021 15:00:52 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:43

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 15:00:52 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:43

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 26 Mar 2021 15:00:52 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 26 Mar 2021 15:00:52 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Mar 2021 15:00:52 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:43

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Mar 2021 15:02:24 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Mar 2021 15:02:24 |
| Data point term sent to Coder | System | 26 Mar 2021 15:02:20 |
| User entered 'Tamsulosin' | (b) (4), (b) (6) | 26 Mar 2021 15:01:37 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:43

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'No (N)' | (b) (4), (b) (6) | 26 Mar 2021 15:01:37 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:43

[Indication](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:15 |
| User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of PROSTATE ISSUES (BPH, ENLARGED) worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM). | (b) (4), (b) (6) | 19 Apr 2021 13:31:46 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of PROSTATE ISSUES (BPH, ENLARGED) worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' answered with 'no worsening reported' (Site from DM). | Samantha Wheeler (b) (4) | 08 Apr 2021 13:11:17 |
| User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of PROSTATE ISSUES (BPH, ENLARGED) worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM). | (b) (4), (b) (6) | 07 Apr 2021 08:10:57 |
| User entered 'BPH' | (b) (4), (b) (6) | 26 Mar 2021 15:01:37 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:43

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '0.4' | (b) (4), (b) (6) | 26 Mar 2021 15:01:37 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:43

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 26 Mar 2021 15:01:37 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:43

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4), (b) (6) | 26 Mar 2021 15:01:37 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:43

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 26 Mar 2021 15:01:37 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:43

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:15 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 26 Mar 2021 15:01:37 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:43

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 26 Mar 2021 15:01:37 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:43

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4), (b) (6) | 26 Mar 2021 15:01:37 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '25 Feb 2021' | (b) (4), (b) (6) | 26 Mar 2021 15:01:37 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '0' | (b) (4), (b) (6) | 26 Mar 2021 15:01:37 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:43

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'No (N)' | (b) (4), (b) (6) | 26 Mar 2021 15:01:37 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:43

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:15 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| User entered '7 Mar 2021' | (b) (4), (b) (6) | 26 Mar 2021 15:01:37 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:43

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'No (N)' | (b) (4), (b) (6) | 26 Mar 2021 15:01:37 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:43

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:15 |
| | | |
| User entered '1' | System | 26 Mar 2021 15:01:37 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:15 |
| | | |
| User entered '1' | System | 26 Mar 2021 15:01:37 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:15 |
| | | |
| User entered '804 (804)' | System | 26 Mar 2021 15:01:37 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:43

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:23 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: OTHER ANTIBACTERIALS, PRODUCT: LINEZOLID - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 07 Apr 2021 15:53:42 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 07 Apr 2021 15:53:42 |
| | (b) (4) | |
| Data point term sent to Coder | System | 26 Mar 2021 15:03:25 |
| User entered 'Linezoid' | (b) (4), (b) (6) | 26 Mar 2021 15:02:27 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:43

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:23 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| User entered 'No (N)' | (b) (4), (b) (6) | 26 Mar 2021 15:02:27 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:43

[Indication](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:23 |
| User closed 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 if appropriate. ' (Site from DM). | (b) (4), (b) (6) | 26 Apr 2021 10:19:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| 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 if appropriate. ' answered with 'this is an SAE and is recorded' (Site from DM). | Samantha Wheeler (b) (4) | 08 Apr 2021 13:10:56 |
| 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 if appropriate. ' (Site from DM). | (b) (4), (b) (6) | 07 Apr 2021 08:11:15 |
| User entered 'MSSA Bacteremia' | (b) (4), (b) (6) | 26 Mar 2021 15:02:27 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:43

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '600' | (b) (4), (b) (6) | 26 Mar 2021 15:02:27 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:43

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 26 Mar 2021 15:02:27 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:43

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4), (b) (6) | 26 Mar 2021 15:02:27 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:43

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:23 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| User entered 'twice daily (BID)' | (b) (4), (b) (6) | 26 Mar 2021 15:02:27 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:43

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4), (b) (6) | 26 Mar 2021 15:02:27 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:43

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:23 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 26 Mar 2021 15:02:27 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:43

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4), (b) (6) | 26 Mar 2021 15:02:27 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '1 Mar 2021' | (b) (4), (b) (6) | 26 Mar 2021 15:02:27 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '0' | (b) (4), (b) (6) | 26 Mar 2021 15:02:27 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:43

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'No (N)' | (b) (4), (b) (6) | 26 Mar 2021 15:02:27 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:43

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:23 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| User entered '7 Mar 2021' | (b) (4), (b) (6) | 26 Mar 2021 15:02:27 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:43

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'No (N)' | (b) (4), (b) (6) | 26 Mar 2021 15:02:27 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:43

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:23 |
| | | |
| User entered '2' | System | 26 Mar 2021 15:02:27 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:23 |
| | | |
| User entered '1' | System | 26 Mar 2021 15:02:27 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:23 |
| | | |
| User entered '804 (804)' | System | 26 Mar 2021 15:02:27 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:43

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: CEFTIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 29 Mar 2021 07:48:12 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 29 Mar 2021 07:48:12 |
| Data point term sent to Coder | System | 26 Mar 2021 15:03:26 |
| User entered 'Ceftin' | (b) (4), (b) (6) | 26 Mar 2021 15:03:04 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:43

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 15:03:04 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:43

[Indication](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'E. Coli UTI' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 15:03:04 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:43

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '250' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 15:03:04 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:43

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 15:03:04 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:43

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 15:03:04 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:43

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'twice daily (BID)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 15:03:04 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:43

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 15:03:04 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:43

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 26 Mar 2021 15:03:10 |
| User entered 'Oral (ORAL)' reason for change: Data Entry Error | (b) (4), (b) (6) | 26 Mar 2021 15:03:10 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 26 Mar 2021 15:03:04 |
| User entered empty. | (b) (4), (b) (6) | 26 Mar 2021 15:03:04 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:43

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 15:03:04 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '18 Mar 2021' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 15:03:04 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 15:03:04 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:43

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 29 Mar 2021 18:53:49 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 26 Mar 2021 15:03:04 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:43

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '29 Mar 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 29 Mar 2021 18:53:49 |
| User entered empty. | (b) (4), (b) (6) | 26 Mar 2021 15:03:04 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:43

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 15:03:04 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:43

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 26 Mar 2021 15:03:04 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Mar 2021 15:03:04 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Mar 2021 15:03:04 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:43

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FOURTH-GENERATION CEPHALOSPORINS, PRODUCT: CEFEPIME HYDROCHLORIDE, PRODUCTSYNONYM: MAXIPIME - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Mar 2021 15:06:25 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Mar 2021 15:06:25 |
| Data point term sent to Coder | System | 26 Mar 2021 15:04:31 |
| User entered 'Maxipime' | (b) (4), (b) (6) | 26 Mar 2021 15:03:59 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:43

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'No (N)' | (b) (4), (b) (6) | 26 Mar 2021 15:03:59 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:43

[Indication](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'E. Coli UTI' | (b) (4), (b) (6) | 26 Mar 2021 15:03:59 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:43

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '2' | (b) (4), (b) (6) | 26 Mar 2021 15:03:59 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:43

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'g (g)' | (b) (4), (b) (6) | 26 Mar 2021 15:03:59 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:43

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered empty. | (b) (4), (b) (6) | 26 Mar 2021 15:03:59 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:43

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'once (ONCE)' | (b) (4), (b) (6) | 26 Mar 2021 15:03:59 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:43

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:27 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 26 Mar 2021 15:03:59 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:43

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'Intravenous (INTRAVENOUS)' | (b) (4), (b) (6) | 26 Mar 2021 15:03:59 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:43

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:27 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 26 Mar 2021 15:03:59 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:27 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| User entered '14 Mar 2021' | (b) (4), (b) (6) | 26 Mar 2021 15:03:59 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '0' | (b) (4), (b) (6) | 26 Mar 2021 15:03:59 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:43

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'No (N)' | (b) (4), (b) (6) | 26 Mar 2021 15:03:59 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:43

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '14 Mar 2021' | (b) (4), (b) (6) | 26 Mar 2021 15:03:59 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:43

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'No (N)' | (b) (4), (b) (6) | 26 Mar 2021 15:03:59 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:43

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:27 |
| | | |
| User entered empty. | System | 26 Mar 2021 15:03:59 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:27 |
| | | |
| User entered empty. | System | 26 Mar 2021 15:03:59 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:27 |
| | | |
| User entered empty. | System | 26 Mar 2021 15:03:59 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:43

Name of Medication

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| 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) | 26 Mar 2021 15:24:26 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 26 Mar 2021 15:24:26 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 26 Mar 2021 15:09:27 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 26 Mar 2021 15:09:27 |
| Data point term sent to Coder | System | 26 Mar 2021 15:07:32 |
| User entered 'Flu Vaccine' | (b) (4), (b) (6) | 26 Mar 2021 15:07:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:43

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:31 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| User entered 'No (N)' | (b) (4), (b) (6) | 26 Mar 2021 15:07:07 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:43

[Indication](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'prophylaxis' | (b) (4), (b) (6) | 26 Mar 2021 15:07:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:43

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'l' | (b) (4), (b) (6) | 26 Mar 2021 15:07:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:43

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:31 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| User entered 'Other (OTHER)' | (b) (4), (b) (6) | 26 Mar 2021 15:07:07 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:43

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'injection' | (b) (4), (b) (6) | 26 Mar 2021 15:07:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:43

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'once (ONCE)' | (b) (4), (b) (6) | 26 Mar 2021 15:07:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:43

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:31 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 26 Mar 2021 15:07:07 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:43

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4), (b) (6) | 26 Mar 2021 15:07:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:43

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:31 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 26 Mar 2021 15:07:07 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:43

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '14 Oct 2020' | (b) (4), (b) (6) | 26 Mar 2021 15:07:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:43

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:31 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| User entered '0' | (b) (4), (b) (6) | 26 Mar 2021 15:07:07 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:43

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:31 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| User entered 'No (N)' | (b) (4), (b) (6) | 26 Mar 2021 15:07:07 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:43

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:31 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| | | |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| User entered '14 Oct 2020' | (b) (4), (b) (6) | 26 Mar 2021 15:07:07 |
| | | |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:43

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 13:20:38 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'No (N)' | (b) (4), (b) (6) | 26 Mar 2021 15:07:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:43

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:31 |
| | | |
| User entered empty. | System | 26 Mar 2021 15:07:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:31 |
| | | |
| User entered empty. | System | 26 Mar 2021 15:07:07 |

US3762120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:41:43

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:34:31 |
| | | |
| User entered empty. | System | 26 Mar 2021 15:07:07 |

US3762120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:41:43

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 05:37:03 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | 25 Feb 2021 15:27:39 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Feb 2021 16:59:25 |
| User entered 'No (N)' | (b) (4), (b) (6) | 10 Feb 2021 15:51:54 |

US3762120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:41:43

Procedure/Surgery date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:27:55 |
| User entered '22 Feb 2021' | (b) (4), (b) (6) | 22 Feb 2021 16:59:47 |

US3762120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:41:43

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | 25 Feb 2021 15:27:55 |
| User entered 'Cystoscopy with stent in right ureter' | (b) (4), (b) (6) | 22 Feb 2021 16:59:47 |

US3762120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:41:43

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:27:55 |
| User entered 'Adverse Event (AE)' | (b) (4), (b) (6) | 22 Feb 2021 16:59:47 |
| | | |

US3762120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:41:43

[If indication is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:27:55 |
| User entered empty. | (b) (4), (b) (6) | 22 Feb 2021 16:59:47 |
| | | |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered | System | 22 Feb 2021 19:21:18 |
| 'USA-US130-2021-MRNA-1273-P301000005' | | |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

Serious

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'John' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Sanders' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered '100 Medical Center Blvd' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: City](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Winston-Salem' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'NC' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered '27157' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Mar 2021 14:10:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| User entered 'US' | System | 22 Feb 2021 19:21:47 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '8' | System | 09 Apr 2021 12:19:12 |
| User entered '7' | System | 08 Apr 2021 20:10:19 |
| User entered '6' | System | 30 Mar 2021 11:52:16 |
| User entered '5' | System | 26 Mar 2021 13:16:25 |
| User entered '4' | System | 24 Mar 2021 22:43:52 |
| User entered '3' | System | 24 Mar 2021 20:52:45 |
| User entered '2' | System | 18 Mar 2021 14:10:28 |
| User entered '1' | System | 22 Feb 2021 19:21:47 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered | System | 22 Feb 2021 19:21:18 |
| 'USA-US130-2021-MRNA-1273-P301000005' | | |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

Serious

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'John' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| | | |
| User entered 'Sanders' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered '100 Medical Center Blvd' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: City](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Winston-Salem' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'NC' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered '27157' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Mar 2021 14:10:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| User entered 'US' | System | 22 Feb 2021 19:21:47 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '8' | System | 09 Apr 2021 12:19:12 |
| User entered '7' | System | 08 Apr 2021 20:10:19 |
| User entered '6' | System | 30 Mar 2021 11:52:16 |
| User entered '5' | System | 26 Mar 2021 13:16:25 |
| User entered '4' | System | 24 Mar 2021 22:43:52 |
| User entered '3' | System | 24 Mar 2021 20:52:45 |
| User entered '2' | System | 18 Mar 2021 14:10:28 |
| User entered '1' | System | 22 Feb 2021 19:21:47 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:41:43

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| User entered '22/Feb/2021 13:21' | System | 22 Feb 2021 19:21:47 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:41:43

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. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| Reviewed for Safety. | (b) (4) | |
| | (b) (4), (b) (6) | 18 Mar 2021 14:10:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| User entered 'I' | (b) (4), (b) (6) | 22 Feb 2021 19:21:47 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'USA-US130-2021-MRNA-1273-P301000005' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

Serious

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'John' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| | | |
| User entered 'Sanders' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered '100 Medical Center Blvd' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: City](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Winston-Salem' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'NC' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered '27157' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Mar 2021 14:10:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| User entered 'US' | System | 22 Feb 2021 19:21:47 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '8' | System | 09 Apr 2021 12:19:12 |
| User entered '7' | System | 08 Apr 2021 20:10:19 |
| User entered '6' | System | 30 Mar 2021 11:52:16 |
| User entered '5' | System | 26 Mar 2021 13:16:25 |
| User entered '4' | System | 24 Mar 2021 22:43:52 |
| User entered '3' | System | 24 Mar 2021 20:52:45 |
| User entered '2' | System | 18 Mar 2021 14:10:28 |
| User entered '1' | System | 22 Feb 2021 19:21:47 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:41:43

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Mar 2021 18:06:57 |
| User entered '18/Mar/2021 10:10' | System | 18 Mar 2021 14:10:28 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:41:43

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. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| Reviewed for Safety. | (b) (4) | |
| | (b) (4), (b) (6) | 24 Mar 2021 20:52:21 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Mar 2021 18:06:57 |
| User entered 'I' | (b) (4), (b) (6) | 18 Mar 2021 14:10:28 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'USA-US130-2021-MRNA-1273-P301000005' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'John' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Sanders' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered '100 Medical Center Blvd' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: City](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Winston-Salem' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'NC' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered '27157' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Mar 2021 14:10:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| User entered 'US' | System | 22 Feb 2021 19:21:47 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '8' | System | 09 Apr 2021 12:19:12 |
| User entered '7' | System | 08 Apr 2021 20:10:19 |
| User entered '6' | System | 30 Mar 2021 11:52:16 |
| User entered '5' | System | 26 Mar 2021 13:16:25 |
| User entered '4' | System | 24 Mar 2021 22:43:52 |
| User entered '3' | System | 24 Mar 2021 20:52:45 |
| User entered '2' | System | 18 Mar 2021 14:10:28 |
| User entered '1' | System | 22 Feb 2021 19:21:47 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:41:43

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 13:22:56 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '24/Mar/2021 16:52' | (b) (4) System | 24 Mar 2021 20:52:45 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:41:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 13:22:56 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Mar 2021 22:43:30 |
| User entered 'I' | (b) (4), (b) (6) | 24 Mar 2021 20:52:45 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered | System | 22 Feb 2021 19:21:18 |
| 'USA-US130-2021-MRNA-1273-P301000005' | | |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

Serious

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'John' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| | | |
| User entered 'Sanders' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered '100 Medical Center Blvd' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: City](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Winston-Salem' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'NC' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered '27157' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Mar 2021 14:10:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| User entered 'US' | System | 22 Feb 2021 19:21:47 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '8' | System | 09 Apr 2021 12:19:12 |
| User entered '7' | System | 08 Apr 2021 20:10:19 |
| User entered '6' | System | 30 Mar 2021 11:52:16 |
| User entered '5' | System | 26 Mar 2021 13:16:25 |
| User entered '4' | System | 24 Mar 2021 22:43:52 |
| User entered '3' | System | 24 Mar 2021 20:52:45 |
| User entered '2' | System | 18 Mar 2021 14:10:28 |
| User entered '1' | System | 22 Feb 2021 19:21:47 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:41:43

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 13:22:56 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '24/Mar/2021 22:43' | (b) (4) System | 24 Mar 2021 22:43:52 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:41:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 13:22:56 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 20:09:55 |
| User entered 'I' | (b) (4), (b) (6) | 24 Mar 2021 22:43:52 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'USA-US130-2021-MRNA-1273-P301000005' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

Serious

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'John' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Sanders' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered '100 Medical Center Blvd' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: City](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Winston-Salem' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'NC' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered '27157' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Mar 2021 14:10:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| User entered 'US' | System | 22 Feb 2021 19:21:47 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '8' | System | 09 Apr 2021 12:19:12 |
| User entered '7' | System | 08 Apr 2021 20:10:19 |
| User entered '6' | System | 30 Mar 2021 11:52:16 |
| User entered '5' | System | 26 Mar 2021 13:16:25 |
| User entered '4' | System | 24 Mar 2021 22:43:52 |
| User entered '3' | System | 24 Mar 2021 20:52:45 |
| User entered '2' | System | 18 Mar 2021 14:10:28 |
| User entered '1' | System | 22 Feb 2021 19:21:47 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:41:43

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 13:22:56 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '26/Mar/2021 06:16' | (b) (4) System | 26 Mar 2021 13:16:25 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:41:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 13:22:56 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 08 Apr 2021 20:09:55 |
| User entered 'I' | (b) (4), (b) (6) | 26 Mar 2021 13:16:25 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'USA-US130-2021-MRNA-1273-P301000005' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

Serious

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'John' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| | | |
| User entered 'Sanders' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered '100 Medical Center Blvd' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: City](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Winston-Salem' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'NC' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered '27157' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Mar 2021 14:10:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| User entered 'US' | System | 22 Feb 2021 19:21:47 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '8' | System | 09 Apr 2021 12:19:12 |
| User entered '7' | System | 08 Apr 2021 20:10:19 |
| User entered '6' | System | 30 Mar 2021 11:52:16 |
| User entered '5' | System | 26 Mar 2021 13:16:25 |
| User entered '4' | System | 24 Mar 2021 22:43:52 |
| User entered '3' | System | 24 Mar 2021 20:52:45 |
| User entered '2' | System | 18 Mar 2021 14:10:28 |
| User entered '1' | System | 22 Feb 2021 19:21:47 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:41:43

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 13:22:56 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '30/Mar/2021 07:52' | (b) (4) System | 30 Mar 2021 11:52:16 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:41:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 13:22:56 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 20:09:55 |
| User entered 'I' | (b) (4), (b) (6) | 30 Mar 2021 11:52:16 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'USA-US130-2021-MRNA-1273-P301000005' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

Serious

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Feb 2021 19:21:18 |
| | System | |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| | | |
| User entered 'John' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Sanders' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered '100 Medical Center Blvd' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: City](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Winston-Salem' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'NC' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered '27157' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Mar 2021 14:10:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| User entered 'US' | System | 22 Feb 2021 19:21:47 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '8' | System | 09 Apr 2021 12:19:12 |
| User entered '7' | System | 08 Apr 2021 20:10:19 |
| User entered '6' | System | 30 Mar 2021 11:52:16 |
| User entered '5' | System | 26 Mar 2021 13:16:25 |
| User entered '4' | System | 24 Mar 2021 22:43:52 |
| User entered '3' | System | 24 Mar 2021 20:52:45 |
| User entered '2' | System | 18 Mar 2021 14:10:28 |
| User entered '1' | System | 22 Feb 2021 19:21:47 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:41:43

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 13:22:56 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '08/Apr/2021 16:10' | (b) (4) System | 08 Apr 2021 20:10:19 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:41:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 13:22:56 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Apr 2021 12:18:45 |
| User entered 'I' | (b) (4), (b) (6) | 08 Apr 2021 20:10:19 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'USA-US130-2021-MRNA-1273-P301000005' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

Serious

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'No (N)' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'John' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Sanders' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered '100 Medical Center Blvd' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: City](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'Winston-Salem' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered 'NC' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:21:31 |
| User entered '27157' | System | 22 Feb 2021 19:21:18 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Mar 2021 14:10:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:09:32 |
| User entered 'US' | System | 22 Feb 2021 19:21:47 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '8' | System | 09 Apr 2021 12:19:12 |
| User entered '7' | System | 08 Apr 2021 20:10:19 |
| User entered '6' | System | 30 Mar 2021 11:52:16 |
| User entered '5' | System | 26 Mar 2021 13:16:25 |
| User entered '4' | System | 24 Mar 2021 22:43:52 |
| User entered '3' | System | 24 Mar 2021 20:52:45 |
| User entered '2' | System | 18 Mar 2021 14:10:28 |
| User entered '1' | System | 22 Feb 2021 19:21:47 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:41:43

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 13:22:56 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered '09/Apr/2021 08:18' | (b) (4) System | 09 Apr 2021 12:19:12 |

US3762120

Folder: SAE USA-US130-2021-MRNA-1273-P301000005

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:41:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 13:22:56 |
| User signature succeeded. | John Sanders (b) (4) | 12 Apr 2021 18:20:04 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 09 Apr 2021 12:19:12 |