

US3532281 (Prod: Children's Healthcare of Atlanta)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:09:56

All time stamps listed in this document are displayed in GMT

US3532281

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 18:55:02

Generated On: 10 Jun 2021 08:09:56

Participant ID

US3532281

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

US3532281

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 11:10:12

Generated On: 10 Jun 2021 08:09:56

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 10 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 | SCRN |

US3532281

Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 11:10:12

Generated On: 10 Jun 2021 08:09:56

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1951 |
| Age | 69 |
| Age Units | YEARS |
| Age (Derived) | 69 |
| 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 |

US3532281

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 11:10:12

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Date of Informed Consent (*dd MMM yyyy*) 10 SEP 2020

Month and Year of Informed Consent (derived) SEP 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

US3532281

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Feb 2021 11:10:12

Generated On: 10 Jun 2021 08:09:56

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 11:10:12

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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) 02 Apr 2021 18:55:03

Generated On: 10 Jun 2021 08:09:56

| | |
|---|--|
| Condition | HYPERTENSION |
| Start date (dd MMM yyyy) | UN UNK 2013 |
| 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 2013 |
| Start Year (derived) | 2013 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 02 Apr 2021 18:55:03

Generated On: 10 Jun 2021 08:09:56

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 02 Apr 2021 18:55:03

Generated On: 10 Jun 2021 08:09:56

| | |
|---|--|
| Condition | ERECTILE DYSFUNCTION |
| Start date (dd MMM yyyy) | UN UNK 2017 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2017 |
| Start Year (derived) | 2017 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

US3532281

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 02 Apr 2021 18:55:03

Generated On: 10 Jun 2021 08:09:56

| | |
|---|--|
| Condition | DEPRESSION |
| Start date (dd MMM yyyy) | UN UNK 2005 |
| 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 2005 |
| Start Year (derived) | 2005 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 02 Apr 2021 18:55:03

Generated On: 10 Jun 2021 08:09:56

| | |
|---|--|
| Condition | KNEE REPLACEMENT - RIGHT KNEE |
| 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 2010 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2010 |
| Start Year (derived) | 2010 |
| Stop Month and Year (derived) | JAN 2010 |
| Stop Year (derived) | 2010 |

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 02 Apr 2021 18:55:03

Generated On: 10 Jun 2021 08:09:56

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 02 Apr 2021 18:55:03

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| | |
|---|--|
| Condition | REVISION SURGERY (BACK SURGERY) |
| Start date (dd MMM yyyy) | 01 JAN 2018 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | 01 JAN 2018 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2018 |
| Start Year (derived) | 2018 |
| Stop Month and Year (derived) | JAN 2018 |
| Stop Year (derived) | 2018 |

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 02 Apr 2021 18:55:03

Generated On: 10 Jun 2021 08:09:56

| | |
|---|--|
| Condition | FIFTH MEDITARSAL BREAK |
| Start date (dd MMM yyyy) | 31 AUG 2020 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | AUG 2020 |
| Start Year (derived) | 2020 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 02 Apr 2021 18:55:03

Generated On: 10 Jun 2021 08:09:56

| | |
|---|--|
| Condition | MENISCUS TRANSPLANT |
| Start date (dd MMM yyyy) | UN UNK 1994 |
| 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 1994 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1994 |
| Start Year (derived) | 1994 |
| Stop Month and Year (derived) | JAN 1994 |
| Stop Year (derived) | 1994 |

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 02 Apr 2021 18:55:03

Generated On: 10 Jun 2021 08:09:56

| | |
|---|--|
| Condition | FEMORAL OSTEOTOMY |
| Start date (dd MMM yyyy) | UN UNK 1994 |
| 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 1994 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1994 |
| Start Year (derived) | 1994 |
| Stop Month and Year (derived) | JAN 1994 |
| Stop Year (derived) | 1994 |

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 02 Apr 2021 18:55:03

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| | |
|---|--|
| Condition | OSTEOARTHRITIS |
| Start date (dd MMM yyyy) | UN UNK 2005 |
| 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 2005 |
| Start Year (derived) | 2005 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 02 Apr 2021 18:55:03

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| | |
|---|--|
| Condition | HEARING LOSS |
| Start date (dd MMM yyyy) | UN UNK 2014 |
| 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 2014 |
| Start Year (derived) | 2014 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 02 Apr 2021 18:55:03

Generated On: 10 Jun 2021 08:09:56

| | |
|---|--|
| Condition | ATTENTION DEFICIT HYPERACTIVITY DISORDER |
| Start date (dd MMM yyyy) | UN UNK 2012 |
| 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 2012 |
| Start Year (derived) | 2012 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 02 Apr 2021 18:55:03

Generated On: 10 Jun 2021 08:09:56

| | |
|---|--|
| Condition | SEASON ALLERGIES |
| 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 (15)

Data signed: (b) (4) 02 Apr 2021 18:55:03

Generated On: 10 Jun 2021 08:09:56

| | |
|---|--|
| Condition | DERMAL FILLER INJECTION |
| Start date (dd MMM yyyy) | UN UNK 2015 |
| 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 2015 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2015 |
| Start Year (derived) | 2015 |
| Stop Month and Year (derived) | JAN 2015 |
| Stop Year (derived) | 2015 |

US3532281

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 11:10:12

Generated On: 10 Jun 2021 08:09:56

| | |
|---|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 10 SEP 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 13:20 (24 HR) |
| Vital Signs Date and Time (derived) | 10 SEP 2020 13:20 |
| Height (<i>xxx.x</i>) | 174 cm |
| Weight (<i>xxx.x</i>) | 77 kg |
| BMI (<i>xxx.x</i>) | 25.43269 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) 22 Feb 2021 11:10:12

Generated On: 10 Jun 2021 08:09:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 11:10:12

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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

LANDSCAPING BUSINESS
DAILY MULTIPLE PERSON
CONTACT

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 11:10:12

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

US3532281

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:34:03

Generated On: 10 Jun 2021 08:09:56

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 10 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 | VISIT1 |

US3532281

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 20:34:03

Generated On: 10 Jun 2021 08:09:56

What was the date of randomization? (dd MMM yyyy) 10 SEP 2020

What was the participant's randomization number? 190539

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 20:34:03

Generated On: 10 Jun 2021 08:09:56

| | |
|--------|---------------|
| 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 20:34:03

Generated On: 10 Jun 2021 08:09:56

| | |
|-------------------------------------|--|
| 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) | 10 SEP 2020 |
| Time of assessment (00:00-23:59) | 13:20 (24 HR) |
| Vital Signs Date and Time (derived) | 10 SEP 2020 13:20 |
| Temperature (xxx.x) | 97.3 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 66 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 144 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 90 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:34:03

Generated On: 10 Jun 2021 08:09:56

| | |
|-------------------------------------|--|
| 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) | 10 SEP 2020 |
| Time of assessment (00:00-23:59) | 15:13 (24 HR) |
| Vital Signs Date and Time (derived) | 10 SEP 2020 15:13 |
| Temperature (xxx.x) | 97.0 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 64 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 142 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 90 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 20:34:03

Generated On: 10 Jun 2021 08:09:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 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: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:34:03

Generated On: 10 Jun 2021 08:09:56

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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 14:38 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 14:38

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 20:34:03

Generated On: 10 Jun 2021 08:09:56

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 10 SEP 2020 |
| Collection time (00:00-23:59) | 14:20 (24 HR) |
| Collection date and time (derived) | 10 SEP 2020 14:20 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:34:03

Generated On: 10 Jun 2021 08:09:56

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 10 SEP 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 14:03 | 10 SEP 2020 14:03 |
| Nasopharyngeal Swab 2 | No | | |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:34:03

Generated On: 10 Jun 2021 08:09:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 15:15

PC Open Date & Time

10 SEP 2020 13:40

PC Close Date & Time

10 SEP 2020 16:10

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °F

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 10 SEP 2020 22:38 |
| PC Open Date & Time | 10 SEP 2020 17:05 |
| PC Close Date & Time | 11 SEP 2020 11:59 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

11 SEP 2020 21:37

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 22:34

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:56

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

13 SEP 2020 20:34

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 22:39

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:56

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

15 SEP 2020 19:15

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:56

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 09:35

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 15:16

PC Open Date & Time

10 SEP 2020 13:40

PC Close Date & Time

10 SEP 2020 16:10

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

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

10 SEP 2020 22:39

PC Open Date & Time

10 SEP 2020 17:05

PC Close Date & Time

11 SEP 2020 11:59

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 21:38

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 22:35

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 20:35

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:56

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

14 SEP 2020 22:39

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 19:16

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 09:36

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 10 SEP 2020 15:17 |
| PC Open Date & Time | 10 SEP 2020 13:40 |
| PC Close Date & Time | 10 SEP 2020 16:10 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 10 SEP 2020 22:40 |
| PC Open Date & Time | 10 SEP 2020 17:05 |
| PC Close Date & Time | 11 SEP 2020 11:59 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 11 SEP 2020 21:39 |
| PC Open Date & Time | 11 SEP 2020 12:00 |
| PC Close Date & Time | 12 SEP 2020 11:59 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

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 ☒

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 12 SEP 2020 22:36 |
| PC Open Date & Time | 12 SEP 2020 12:00 |
| PC Close Date & Time | 13 SEP 2020 11:59 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

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 ☒

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 13 SEP 2020 20:35 |
| PC Open Date & Time | 13 SEP 2020 12:00 |
| PC Close Date & Time | 14 SEP 2020 11:59 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

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 ☒

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 14 SEP 2020 22:40 |
| PC Open Date & Time | 14 SEP 2020 12:00 |
| PC Close Date & Time | 15 SEP 2020 11:59 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

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

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EAB) (1725)

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 15 SEP 2020 19:17 |
| PC Open Date & Time | 15 SEP 2020 12:00 |
| PC Close Date & Time | 16 SEP 2020 11:59 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

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 ☒

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 17 SEP 2020 09:36 |
| PC Open Date & Time | 16 SEP 2020 12:00 |
| PC Close Date & Time | 17 SEP 2020 11:59 |

US3532281

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 11:10:12

Generated On: 10 Jun 2021 08:09:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532281

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 11:10:12

Generated On: 10 Jun 2021 08:09:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532281

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 11:10:12

Generated On: 10 Jun 2021 08:09:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532281

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 11:10:12

Generated On: 10 Jun 2021 08:09:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532281

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 11:10:12

Generated On: 10 Jun 2021 08:09:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532281

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 11:10:12

Generated On: 10 Jun 2021 08:09:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532281

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:34:03

Generated On: 10 Jun 2021 08:09:56

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 6 OCT 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT2 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:34:03

Generated On: 10 Jun 2021 08:09:56

| | |
|-------------------------------------|---|
| 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) | 6 OCT 2020 |
| Time of assessment (00:00-23:59) | 14:25 (24 HR) |
| Vital Signs Date and Time (derived) | 6 OCT 2020 14:25 |
| 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) | 71 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 138 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 77 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:34:03

Generated On: 10 Jun 2021 08:09:56

| | |
|-------------------------------------|---|
| 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) | 6 OCT 2020 |
| Time of assessment (00:00-23:59) | 16:03 (24 HR) |
| Vital Signs Date and Time (derived) | 6 OCT 2020 16:03 |
| Temperature (xxx.x) | 98.5 F |
| Route of measurement | Oral <input checked="" type="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 66 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 136 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 79 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:34:03

Generated On: 10 Jun 2021 08:09:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 OCT 2020

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

US3532281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:34:03

Generated On: 10 Jun 2021 08:09:56

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) 6 OCT 2020

What was the treatment time? (00:00-23:59) 15:27 (24 HR)

Treatment Date and Time (derived) 6 OCT 2020 15:27

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

US3532281

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:34:03

Generated On: 10 Jun 2021 08:09:56

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

6 OCT 2020

Collection time (00:00-23:59)

15:00 (24 HR)

Collection date and time (derived)

6 OCT 2020 15:00

US3532281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:34:03

Generated On: 10 Jun 2021 08:09:56

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 6 OCT 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 14:45 | 6 OCT 2020 14:45 |
| Nasopharyngeal Swab 2 | No | | |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:34:03

Generated On: 10 Jun 2021 08:09:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 16:02

PC Open Date & Time

06 OCT 2020 15:47

PC Close Date & Time

06 OCT 2020 18:17

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °F

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 06 OCT 2020 21:41 |
| PC Open Date & Time | 06 OCT 2020 19:12 |
| PC Close Date & Time | 07 OCT 2020 11:59 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

| | |
|--|--------------------------------------|
| Was TEMPERATURE taken? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Please record your TEMPERATURE in °F | 99.7 °F |
| Was any MEDICATION TAKEN today for pain or fever? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 07 OCT 2020 15:31 |
| PC Open Date & Time | 07 OCT 2020 12:00 |
| PC Close Date & Time | 08 OCT 2020 11:59 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 OCT 2020 02:46

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:56

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

98.2 °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

09 OCT 2020 18:14

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 02:07

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:56

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

98.7 °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

11 OCT 2020 22:22

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 23:21

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 16:03

PC Open Date & Time

06 OCT 2020 15:47

PC Close Date & Time

06 OCT 2020 18:17

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

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

06 OCT 2020 21:42

PC Open Date & Time

06 OCT 2020 19:12

PC Close Date & Time

07 OCT 2020 11:59

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 15:32

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 OCT 2020 02:47

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 OCT 2020 18:15

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:56

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

11 OCT 2020 02:07

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 OCT 2020 22:23

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:56

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

12 OCT 2020 23:21

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 06 OCT 2020 16:04 |
| PC Open Date & Time | 06 OCT 2020 15:47 |
| PC Close Date & Time | 06 OCT 2020 18:17 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 06 OCT 2020 21:42 |
| PC Open Date & Time | 06 OCT 2020 19:12 |
| PC Close Date & Time | 07 OCT 2020 11:59 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

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 ☒

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 07 OCT 2020 15:35 |
| PC Open Date & Time | 07 OCT 2020 12:00 |
| PC Close Date & Time | 08 OCT 2020 11:59 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

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 ☒

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 09 OCT 2020 02:47 |
| PC Open Date & Time | 08 OCT 2020 12:00 |
| PC Close Date & Time | 09 OCT 2020 11:59 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

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 ☒

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 09 OCT 2020 18:15 |
| PC Open Date & Time | 09 OCT 2020 12:00 |
| PC Close Date & Time | 10 OCT 2020 11:59 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

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 ☒

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 11 OCT 2020 02:08 |
| PC Open Date & Time | 10 OCT 2020 12:00 |
| PC Close Date & Time | 11 OCT 2020 11:59 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

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

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EAB) (1725)

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

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

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

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)

112 of 2312

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 12 OCT 2020 23:21 |
| PC Open Date & Time | 12 OCT 2020 12:00 |
| PC Close Date & Time | 13 OCT 2020 11:59 |

US3532281

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 11:10:12

Generated On: 10 Jun 2021 08:09:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532281

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 11:10:12

Generated On: 10 Jun 2021 08:09:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532281

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:34:03

Generated On: 10 Jun 2021 08:09:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532281

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:34:03

Generated On: 10 Jun 2021 08:09:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532281

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:34:03

Generated On: 10 Jun 2021 08:09:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532281

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:34:03

Generated On: 10 Jun 2021 08:09:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532281

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:34:03

Generated On: 10 Jun 2021 08:09:56

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

US3532281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:34:04

Generated On: 10 Jun 2021 08:09:56

| | |
|-------------------------------------|---------------------------------------|
| 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) | 14:17 (24 HR) |
| Vital Signs Date and Time (derived) | 04 NOV 2020 14:17 |
| Temperature (xxx.x) | 97.5 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 65 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 147 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 86 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:34:03

Generated On: 10 Jun 2021 08:09:56

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.

US3532281

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:34:03

Generated On: 10 Jun 2021 08:09:56

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 04 NOV 2020 |
| Collection time (00:00-23:59) | 14:24 (24 HR) |
| Collection date and time (derived) | 04 NOV 2020 14:24 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:34:03

Generated On: 10 Jun 2021 08:09:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532281

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 NOV 2020 17:59:37

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3532281

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

17 NOV 2020 13:08:58

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| TIMEPOINT | DAY 75 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 21 NOV 2020 09:50:31 |
| Patient Cloud Open Date & Time | 21 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 25 NOV 2020 23:59 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| 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 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 | 30 NOV 2020 15:49:31 |
| Patient Cloud Open Date & Time | 28 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 02 DEC 2020 23:59 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

05 DEC 2020 09:22:10

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| 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 | 12 DEC 2020 00:58:04 |
| Patient Cloud Open Date & Time | 12 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 16 DEC 2020 23:59 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

19 DEC 2020 10:23:46

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

26 DEC 2020 00:04:51

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

02 JAN 2021 11:11:08

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| TIMEPOINT | DAY 124 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 | 10 JAN 2021 00:58:48 |
| Patient Cloud Open Date & Time | 09 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 13 JAN 2021 23:59 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

16 JAN 2021 04:09:31

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

23 JAN 2021 00:02:05

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

30 JAN 2021 10:25:02

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| TIMEPOINT | DAY 152 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 | 06 FEB 2021 09:47:54 |
| Patient Cloud Open Date & Time | 06 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 10 FEB 2021 23:59 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 12:18:03

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| | |
|---|--|
| TIMEPOINT | DAY 166 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 | 22 FEB 2021 12:22:35 |
| Patient Cloud Open Date & Time | 20 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 24 FEB 2021 23:59 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

27 FEB 2021 14:29:35

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| TIMEPOINT | DAY 180 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 06 MAR 2021 18:58:31 |
| Patient Cloud Open Date & Time | 06 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 10 MAR 2021 23:59 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

16 MAR 2021 16:32:04

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

23 MAR 2021 17:26:37

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| 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 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 | 27 MAR 2021 08:50:00 |
| Patient Cloud Open Date & Time | 27 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 31 MAR 2021 23:59 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

03 APR 2021 09:04:00

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 08:15:14

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

17 APR 2021 00:20:24

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

24 APR 2021 13:57:01

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| | |
|---|--|
| TIMEPOINT | DAY 236 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 | 01 MAY 2021 06:57:53 |
| Patient Cloud Open Date & Time | 01 MAY 2021 00:01 |
| Patient Cloud Close Date & Time | 05 MAY 2021 23:59 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| TIMEPOINT | DAY 243 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| TIMEPOINT | DAY 250 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| 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"/> |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| TIMEPOINT | DAY 271 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| TIMEPOINT | DAY 299 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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°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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| 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"/> |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 21 AUG 2021 00:01 |
| Patient Cloud Close Date & Time | 25 AUG 2021 23:59 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| TIMEPOINT | DAY 362 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| TIMEPOINT | DAY 376 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 404

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| 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"/> |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| TIMEPOINT | DAY 446 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| 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"/> |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

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

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| 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"/> |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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°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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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°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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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°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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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°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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 16 APR 2022 00:01 |
| Patient Cloud Close Date & Time | 20 APR 2022 23:59 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| 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"/> |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| 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"/> |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| 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"/> |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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 ☐ Yes ☐

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 628

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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°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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| TIMEPOINT | DAY 684 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| TIMEPOINT | DAY 698 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| TIMEPOINT | DAY 719 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 27 AUG 2022 00:01 |
|--|-------------------|

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 31 AUG 2022 23:59 |
|---|-------------------|

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| 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"/> |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| 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"/> |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 15 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 19 OCT 2022 23:59 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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°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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

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

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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°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 ☐

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

| 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"/> |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

US3532281

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:09:56

| 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 |
|---|--|---------------------------|
| Yes | Yes | 27 FEB 2021 14:31:39 |

US3532281

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 17:46:20

Generated On: 10 Jun 2021 08:09:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532281

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 17:46:20

Generated On: 10 Jun 2021 08:09:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532281

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 18:55:03

Generated On: 10 Jun 2021 08:09:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532281

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:55:03

Generated On: 10 Jun 2021 08:09:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532281

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 18:55:03

Generated On: 10 Jun 2021 08:09:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532281

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:55:03

Generated On: 10 Jun 2021 08:09:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532281

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 18:55:03

Generated On: 10 Jun 2021 08:09:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532281

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:55:03

Generated On: 10 Jun 2021 08:09:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532281

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 18:55:03

Generated On: 10 Jun 2021 08:09:56

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 24 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 |
|------------|--------|

US3532281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 18:55:03

Generated On: 10 Jun 2021 08:09:56

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) _____

US3532281

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 18:55:03

Generated On: 10 Jun 2021 08:09:56

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.

US3532281

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 18:55:03

Generated On: 10 Jun 2021 08:09:56

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 24 MAR 2021 |
| Collection time (00:00-23:59) | 14:55 (24 HR) |
| Collection date and time (derived) | 24 MAR 2021 14:55 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:55:03

Generated On: 10 Jun 2021 08:09:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532281

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

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

US3532281

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3532281

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:09:56

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

US3532281

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:09:56

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 18:55:02

Generated On: 10 Jun 2021 08:09:56

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 12 JAN 2021 |
|--------------------------|-------------|

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

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

US3532281

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 18:55:02

Generated On: 10 Jun 2021 08:09:56

Date of updated informed consent (dd MMM yyyy) 12 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 12 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 18:55:02

Generated On: 10 Jun 2021 08:09:56

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 12 JAN 2021 |
| Collection time (00:00-23:59) | 11:54 (24 HR) |
| Collection date and time (derived) | 12 JAN 2021 11:54 |

US3532281

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 18:55:02

Generated On: 10 Jun 2021 08:09:56

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 12 JAN 2021 |
| Collection time (00:00 - 23:59) | 11:43 |
| Collection Date and Time (derived) | 12 JAN 2021 11:43 |

US3532281

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 09:18:50

Generated On: 10 Jun 2021 08:09:56

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

| | |
|--|--|
| AEID | |
| Adverse event | NOSEBLEED |
| Was this a medically-attended AE? | Yes <input type="radio"/> No <input checked="" 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) | 10 OCT 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 10 OCT 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

| | |
|--|---|
| 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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/> |
| Other action taken (check all that apply) | |
| None | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

| | |
|--|--|
| AEID | USA-US077-2020-MRNA-1273-P30 1000006 |
| Adverse event | WORSENING OF OSTEOARTHRITIS |
| 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) | 23 OCT 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 25 OCT 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 23 OCT 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 25 OCT 2020 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

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

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

SUBJECT HAS
OSTEOARTHRITIS IN THE LEFT
ANKLE THAT HAS BEEN
WORSENING, SUBJECT OPTED
FOR ANKLE REPLACEMENT
SURGERY, WHICH WAS
PERFORMED ON 23OCT2020.PER
SUBJECT, SURGERY HAD BEEN
PLANNED IN JUNE BUT HE
WITHHELD DUE TO COVID.
ADDED AS AE BECAUSE
REQUIRED HOSPITALIZATION
OVER 24 HOURS.

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

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

AEID

Adverse event

POST-SURGICAL PAIN LEFT
ANKLE

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)

23 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

03 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

| | |
|--|---|
| 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 | SUBJECT SUFFERED FROM PAIN AFTER ANKLE SURGERY . |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 08:28:41

Generated On: 10 Jun 2021 08:09:56

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

Name of Medication TELMISARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

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

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

Name of Medication SPIRONOLACTONE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 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 (3)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

Name of Medication TADALAFIL

Prophylaxis Yes ☐
No ☒

Indication ERECTILE DYSFUNCTION

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 (3)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2017 | |
| 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"/> |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

Name of Medication TESTOSTERONE CYPIONATE

Prophylaxis Yes ☐
No ☒

Indication LOW TESTOSTERONE

Dose per administration 06

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

| | | |
|--|--------------------------|----------------------------------|
| | 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) | UN UNK 2010 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input checked="" type="radio"/> |
| | 804 | <input type="radio"/> |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

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

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

Name of Medication VENLAFAXINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2005 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication FEVER (DOCUMENTED IN
EDIARY POST 2ND DOSE

Dose per administration 325

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 (7)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

| | | |
|--|--------------------------|-------------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify | | |
| Start date (dd MMM yyyy) | 7 OCT 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 8 OCT 2020 | |
| Was this medication taken for solicited event? | Yes | <input checked="" type="checkbox"/> |
| | No | <input 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 (8)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication BODY ACHES

Dose per administration 200

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 (8)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

| | | |
|--|--------------------------|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 7 OCT 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 7 OCT 2020 | | |
| Was this medication taken for solicited event? | Yes | <input checked="" type="checkbox"/> |
| | No | <input 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 (9)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication PAIN FROM ANKLE SURGERY

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 (9)

Data signed: (b) (4) 16 Apr 2021 08:40:02

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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) | | 23 OCT 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 29 OCT 2020 |
| 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 (10)

Data signed: (b) (4) 16 Apr 2021 08:40:02

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Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication PAIN FROM ANKLE SURGERY

Dose per administration 975

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 08:40:02

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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) | 23 OCT 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 03 NOV 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 4 | |
| 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 (11)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication DVT PREVENTION AFTER
ANKLE SURGERY

Dose per administration 325

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 (11)

Data signed: (b) (4) 16 Apr 2021 08:40:02

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| | | |
|--|--------------------------|----------------------------------|
| | 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) | 23 OCT 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

Name of Medication POLYETHYLENE GLYCOL

Prophylaxis Yes ☒
No ☐

Indication BOWEL MANAGEMENT
-PREVENTION OF
CONSTIPATION CAUSED BY
PAIN MEDICATION

Dose per administration 17

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

| | | |
|--|--------------------------|-------------------------------------|
| | Transdermal | <input type="checkbox"/> |
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 25 OCT 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 28 OCT 2020 | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

Name of Medication ADDERALL XR

Prophylaxis Yes ☐
No ☒

Indication ADHD

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2012 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

Name of Medication FLONASE

Prophylaxis Yes ☒
No ☐

Indication SEASONAL ALLERGIES

Dose per administration 2

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

If dose unit is Other, specify SPRAYS

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) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

| | | |
|--|--------------------------|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input checked="" type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2019 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="checkbox"/> |
| | No | <input type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| 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 (15)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

Name of Medication MULTIVITAMIN- MEN'S 50

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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) 16 Apr 2021 08:40:02

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2019 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3532281

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 18:55:02

Generated On: 10 Jun 2021 08:09:56

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3532281

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 18:55:02

Generated On: 10 Jun 2021 08:09:56

| Procedure/Surgery date (dd MMM yyyy) | Procedure/Surgery | Indication | If indication is Other, specify |
|---|----------------------------------|-----------------|---------------------------------|
| 23 OCT 2020 | LEFT TOTAL ANKLE ARTHROPLASTY | Medical History | |

US3532281

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:09:56

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

US3532281

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:09:56

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 ☐

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

| | |
|--|--|
| SAEID | USA-US077-2020-MRNA-1273-P301000006 |
| 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 | EVAN |
| Investigator's Last Name | ANDERSON |
| Site Address: Street | 2015 UPPERGATE DRIVE |
| Site Address: City | ATLANTA |
| Site Address: State | GA |
| Site Address: Postal Code | 30323 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 10 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

| | |
|---|--|
| SAEID | USA-US077-2020-MRNA-1273-P301000006 |
| 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 | EVAN |
| Investigator's Last Name | ANDERSON |
| Site Address: Street | 2015 UPPERGATE DRIVE |
| Site Address: City | ATLANTA |
| Site Address: State | GA |
| Site Address: Postal Code | 30323 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 10 |
| Date of submission (Pre-filled from custom function) | 28/OCT/2020 13:09 |
| 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 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

| | |
|---|--|
| SAEID | USA-US077-2020-MRNA-1273-P301000006 |
| 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 | EVAN |
| Investigator's Last Name | ANDERSON |
| Site Address: Street | 2015 UPPERGATE DRIVE |
| Site Address: City | ATLANTA |
| Site Address: State | GA |
| Site Address: Postal Code | 30323 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 10 |
| Date of submission (Pre-filled from custom function) | 09/NOV/2020 19:05 |
| 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 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

| | |
|---|--|
| SAEID | USA-US077-2020-MRNA-1273-P301000006 |
| 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 | EVAN |
| Investigator's Last Name | ANDERSON |
| Site Address: Street | 2015 UPPERGATE DRIVE |
| Site Address: City | ATLANTA |
| Site Address: State | GA |
| Site Address: Postal Code | 30323 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 10 |
| Date of submission (Pre-filled from custom function) | 18/NOV/2020 16:24 |
| 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 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

| | |
|---|--|
| SAEID | USA-US077-2020-MRNA-1273-P301000006 |
| 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 | EVAN |
| Investigator's Last Name | ANDERSON |
| Site Address: Street | 2015 UPPERGATE DRIVE |
| Site Address: City | ATLANTA |
| Site Address: State | GA |
| Site Address: Postal Code | 30323 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 10 |
| Date of submission (Pre-filled from custom function) | 01/DEC/2020 10:30 |
| 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 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

| | |
|---|--|
| SAEID | USA-US077-2020-MRNA-1273-P301000006 |
| 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 | EVAN |
| Investigator's Last Name | ANDERSON |
| Site Address: Street | 2015 UPPERGATE DRIVE |
| Site Address: City | ATLANTA |
| Site Address: State | GA |
| Site Address: Postal Code | 30323 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 10 |
| Date of submission (Pre-filled from custom function) | 06/JAN/2021 16:45 |
| 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 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

| | |
|---|--|
| SAEID | USA-US077-2020-MRNA-1273-P301000006 |
| 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 | EVAN |
| Investigator's Last Name | ANDERSON |
| Site Address: Street | 2015 UPPERGATE DRIVE |
| Site Address: City | ATLANTA |
| Site Address: State | GA |
| Site Address: Postal Code | 30323 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 10 |
| Date of submission (Pre-filled from custom function) | 04/FEB/2021 14:19 |
| 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 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (7)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

| | |
|---|--|
| SAEID | USA-US077-2020-MRNA-1273-P301000006 |
| 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 | EVAN |
| Investigator's Last Name | ANDERSON |
| Site Address: Street | 2015 UPPERGATE DRIVE |
| Site Address: City | ATLANTA |
| Site Address: State | GA |
| Site Address: Postal Code | 30323 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 10 |
| Date of submission (Pre-filled from custom function) | 08/FEB/2021 14:46 |
| 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 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (8)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

| | |
|---|--|
| SAEID | USA-US077-2020-MRNA-1273-P301000006 |
| 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 | EVAN |
| Investigator's Last Name | ANDERSON |
| Site Address: Street | 2015 UPPERGATE DRIVE |
| Site Address: City | ATLANTA |
| Site Address: State | GA |
| Site Address: Postal Code | 30323 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 10 |
| Date of submission (Pre-filled from custom function) | 08/MAR/2021 12:04 |
| 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 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (9)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

| | |
|---|--|
| SAEID | USA-US077-2020-MRNA-1273-P301000006 |
| 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 | EVAN |
| Investigator's Last Name | ANDERSON |
| Site Address: Street | 2015 UPPERGATE DRIVE |
| Site Address: City | ATLANTA |
| Site Address: State | GA |
| Site Address: Postal Code | 30323 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 10 |
| Date of submission (Pre-filled from custom function) | 01/APR/2021 10:23 |
| 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 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (10)

Data signed: (b) (4) 16 Apr 2021 08:40:02

Generated On: 10 Jun 2021 08:09:56

| | |
|---|--|
| SAEID | USA-US077-2020-MRNA-1273-P301000006 |
| 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 | EVAN |
| Investigator's Last Name | ANDERSON |
| Site Address: Street | 2015 UPPERGATE DRIVE |
| Site Address: City | ATLANTA |
| Site Address: State | GA |
| Site Address: Postal Code | 30323 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 10 |
| Date of submission (Pre-filled from custom function) | 09/APR/2021 14:44 |
| 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

US3532281 (Prod: Children's Healthcare of Atlanta)

US3532281

Form: Participant Creation

Generated On: 10 Jun 2021 08:09:56

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'US3532281' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 10 Sep 2020 17:19:28 |

US3532281

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:09:56

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 10 Sep 2020 17:49:14 |

US3532281

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '10 SEP 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 10 Sep 2020 17:19:29 |

US3532281

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Clinic (Clinic)' | Cindy Lubbers (b) (4) | 10 Sep 2020 17:49:14 |

US3532281

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:09:56

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'SCRN' | System | 10 Sep 2020 17:49:14 |

US3532281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:56

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered (b) (6) 1951' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 10 Sep 2020 17:19:30 |

US3532281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:56

[Age](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| 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 | 13 Sep 2020 14:10:31 |
| User entered '69' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 13 Sep 2020 14:10:31 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| User entered empty. | System | 10 Sep 2020 17:51:05 |
| | Cindy Lubbers (b) (4) | 10 Sep 2020 17:51:05 |
| | (b) (4) | |

US3532281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:56

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'YEARS' | System | 13 Sep 2020 14:10:31 |
| User entered empty. | System | 10 Sep 2020 17:51:05 |

US3532281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:56

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '69' | System | 10 Sep 2020 17:53:21 |

US3532281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:56

[Sex](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Male (M)' | Cindy Lubbers (b) (4) | 10 Sep 2020 17:51:05 |

US3532281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:56

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Cindy Lubbers (b) (4) | 10 Sep 2020 17:51:05 |

US3532281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:56

[White](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'I' | Cindy Lubbers (b) (4) | 10 Sep 2020 17:51:05 |

US3532281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:56

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 10 Sep 2020 17:51:05 |

US3532281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:56

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 10 Sep 2020 17:51:05 |

US3532281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:56

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 10 Sep 2020 17:51:05 |

US3532281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:56

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 10 Sep 2020 17:51:05 |

US3532281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:56

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 10 Sep 2020 17:51:05 |

US3532281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:56

If race is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered empty. | Cindy Lubbers (b) (4) | 10 Sep 2020 17:51:05 |

US3532281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:56

[Unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 10 Sep 2020 17:51:05 |

US3532281

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:56

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 10 Sep 2020 17:51:05 |

US3532281

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:56

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '10 Sep 2020' | Cindy Lubbers (b) (4) | 10 Sep 2020 17:53:21 |

US3532281

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'Sep 2020' | System | 10 Sep 2020 17:53:21 |

US3532281

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '2020' | System | 10 Sep 2020 17:53:21 |

US3532281

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:56

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Amendment 3 (3)' | Cindy Lubbers (b) (4) | 10 Sep 2020 17:53:21 |

US3532281

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 10 Sep 2020 18:52:29 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 10 Sep 2020 18:52:29 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 10 Sep 2020 18:52:29 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 10 Sep 2020 17:53:21 |
| User entered empty. | Cindy Lubbers (b) (4) | 10 Sep 2020 17:53:21 |

US3532281

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered empty. | Cindy Lubbers (b) (4) | 10 Sep 2020 17:53:21 |

US3532281

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:56

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered empty. | Cindy Lubbers (b) (4) | 10 Sep 2020 17:53:21 |

US3532281

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:56

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 10 Sep 2020 18:52:29 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 10 Sep 2020 18:52:29 |
| User entered 'No (N)' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 10 Sep 2020 18:52:29 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | 10 Sep 2020 17:53:21 |
| User entered empty. | System | 10 Sep 2020 17:53:21 |
| | Cindy Lubbers (b) (4) | 10 Sep 2020 17:53:21 |
| | (b) (4) | |

US3532281

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:56

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered empty. | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 10 Sep 2020 17:19:29 |

US3532281

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:56

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'I' | System | 10 Sep 2020 18:52:34 |

US3532281

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:52:34 |

US3532281

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:09:56

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:19:47 |

US3532281

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:56

[Condition](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Sep 2020 13:33:34 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Sep 2020 13:33:34 |
| Data point term sent to Coder | System | 11 Sep 2020 13:32:58 |
| User entered 'Hypertension' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:32:23 |

US3532281

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'un UNK 2013' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:32:23 |

US3532281

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:32:23 |

US3532281

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:56

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:32:23 |

US3532281

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:32:23 |

US3532281

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:56

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:32:23 |

US3532281

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'Jan 2013' | System | 11 Sep 2020 13:32:23 |

US3532281

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '2013' | System | 11 Sep 2020 13:32:23 |

US3532281

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered empty. | System | 11 Sep 2020 13:32:23 |

US3532281

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered empty. | System | 11 Sep 2020 13:32:23 |

US3532281

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:56

[Condition](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User coded data point as SOC: Investigations, HLGt: Endocrine investigations (incl sex hormones), HLT: Reproductive hormone analyses, PT: Blood testosterone decreased, LLT: Testosterone low - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Sep 2020 13:33:33 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Sep 2020 13:33:33 |
| Data point term sent to Coder | System | 11 Sep 2020 13:32:58 |
| User entered 'Low testosterone' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:32:52 |

US3532281

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'un UNK 2010' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:32:52 |

US3532281

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:32:52 |

US3532281

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:56

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:32:52 |

US3532281

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:32:52 |

US3532281

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:56

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:32:52 |

US3532281

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:56

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'Jan 2010' | System | 11 Sep 2020 13:32:52 |

US3532281

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '2010' | System | 11 Sep 2020 13:32:52 |

US3532281

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered empty. | System | 11 Sep 2020 13:32:52 |

US3532281

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered empty. | System | 11 Sep 2020 13:32:52 |

US3532281

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:09:56

[Condition](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Sep 2020 13:34:39 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Sep 2020 13:34:39 |
| Data point term sent to Coder | System | 11 Sep 2020 13:33:59 |
| User entered 'Erectile dysfunction' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:33:24 |

US3532281

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'un UNK 2017' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:33:24 |

US3532281

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:33:24 |

US3532281

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:09:56

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:33:24 |

US3532281

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:33:24 |

US3532281

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:09:56

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:33:24 |

US3532281

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'Jan 2017' | System | 11 Sep 2020 13:33:24 |

US3532281

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '2017' | System | 11 Sep 2020 13:33:24 |

US3532281

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered empty. | System | 11 Sep 2020 13:33:24 |

US3532281

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered empty. | System | 11 Sep 2020 13:33:24 |

US3532281

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:09:56

[Condition](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Sep 2020 13:34:39 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Sep 2020 13:34:39 |
| Data point term sent to Coder | System | 11 Sep 2020 13:33:59 |
| User entered 'Depression' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:33:43 |

US3532281

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'un UNK 2005' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:33:43 |

US3532281

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:33:43 |

US3532281

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:09:56

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:33:43 |

US3532281

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:33:43 |

US3532281

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:09:56

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:33:43 |

US3532281

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:09:56

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'Jan 2005' | System | 11 Sep 2020 13:33:43 |

US3532281

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '2005' | System | 11 Sep 2020 13:33:43 |

US3532281

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered empty. | System | 11 Sep 2020 13:33:43 |

US3532281

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered empty. | System | 11 Sep 2020 13:33:43 |

US3532281

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:09:56

[Condition](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee total replacement - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Sep 2020 13:35:43 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Sep 2020 13:35:43 |
| Data point term sent to Coder | System | 11 Sep 2020 13:35:03 |
| User entered 'Knee replacement - right knee' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:34:31 |

US3532281

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'un UNK 2010' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:34:31 |

US3532281

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:34:31 |

US3532281

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:09:56

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:34:31 |

US3532281

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'un UNK 2010' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:34:31 |

US3532281

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:09:56

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:34:31 |

US3532281

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'Jan 2010' | System | 11 Sep 2020 13:34:31 |

US3532281

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:09:56

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '2010' | System | 11 Sep 2020 13:34:31 |

US3532281

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'Jan 2010' | System | 11 Sep 2020 13:34:31 |

US3532281

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '2010' | System | 11 Sep 2020 13:34:31 |

US3532281

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:09:56

Condition

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Spinal fusion surgery - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Sep 2020 14:17:47 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Sep 2020 14:17:47 |
| Data point term sent to Coder | System | 11 Sep 2020 13:35:04 |
| User entered 'Back fusion surgery' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:35:03 |

US3532281

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'un UNK 2019' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:35:03 |

US3532281

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:35:03 |

US3532281

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:09:56

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:35:03 |

US3532281

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'un UNK 2019' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:35:03 |

US3532281

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:09:56

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:35:03 |

US3532281

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:09:56

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'Jan 2019' | System | 11 Sep 2020 13:35:03 |

US3532281

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '2019' | System | 11 Sep 2020 13:35:03 |

US3532281

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'Jan 2019' | System | 11 Sep 2020 13:35:03 |

US3532281

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '2019' | System | 11 Sep 2020 13:35:03 |

US3532281

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:09:56

[Condition](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 30 Oct 2020 06:12:42 |
| Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'done' (Site from DM). | Cindy Lubbers (b) (4) (b) (4) | 27 Oct 2020 17:54:15 |
| User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 05 Oct 2020 05:15:32 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal operation, LLT: Back surgery - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 12 Sep 2020 08:10:46 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 12 Sep 2020 08:10:46 |
| Data point term sent to Coder | System | 11 Sep 2020 13:36:08 |
| User entered 'Revision surgery (back surgery)' | Cindy Lubbers (b) (4) (b) (4) | 11 Sep 2020 13:35:53 |

US3532281

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '01 Jan 2018' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:35:53 |

US3532281

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:35:53 |

US3532281

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:09:56

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:35:53 |

US3532281

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '01 Jan 2018' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:35:53 |

US3532281

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:09:56

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:35:53 |

US3532281

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:09:56

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'Jan 2018' | System | 11 Sep 2020 13:35:53 |

US3532281

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '2018' | System | 11 Sep 2020 13:35:53 |

US3532281

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'Jan 2018' | System | 11 Sep 2020 13:35:53 |

US3532281

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '2018' | System | 11 Sep 2020 13:35:53 |

US3532281

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:09:56

[Condition](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Foot fracture, LLT: Foot fracture - version MedDRA\\23.0. | Coder Import (b) (4) | 16 Sep 2020 13:49:42 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 16 Sep 2020 13:49:42 |
| Data point term sent to Coder | System | 11 Sep 2020 13:37:09 |
| User entered 'Fifth metatarsal break' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:36:43 |

US3532281

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '31 Aug 2020' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:36:43 |

US3532281

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:36:43 |

US3532281

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:09:56

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:36:43 |

US3532281

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:36:43 |

US3532281

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:09:56

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:36:43 |

US3532281

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:09:56

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'Aug 2020' | System | 11 Sep 2020 13:36:43 |

US3532281

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '2020' | System | 11 Sep 2020 13:36:43 |

US3532281

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered empty. | System | 11 Sep 2020 13:36:43 |

US3532281

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered empty. | System | 11 Sep 2020 13:36:43 |

US3532281

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:09:56

[Condition](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee arthroplasty - version MedDRA\\23.0. | Coder Import (b) (4) | 24 Nov 2020 22:17:03 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 24 Nov 2020 22:17:03 |
| Data point term sent to Coder | System | 11 Sep 2020 13:38:10 |
| User entered 'Meniscus transplant' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:37:19 |

US3532281

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'un UNK 1994' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:37:19 |

US3532281

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:37:19 |

US3532281

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:09:56

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:37:19 |

US3532281

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'un UNK 1994' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:37:19 |

US3532281

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:09:56

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:37:19 |

US3532281

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'Jan 1994' | System | 11 Sep 2020 13:37:19 |

US3532281

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:09:56

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '1994' | System | 11 Sep 2020 13:37:19 |

US3532281

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'Jan 1994' | System | 11 Sep 2020 13:37:19 |

US3532281

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '1994' | System | 11 Sep 2020 13:37:19 |

US3532281

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:09:56

[Condition](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Bone therapeutic procedures NEC, PT: Osteotomy, LLT: Osteotomy - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Sep 2020 14:26:43 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Sep 2020 14:26:43 |
| Data point term sent to Coder | System | 11 Sep 2020 13:38:10 |
| User entered 'Femoral osteotomy' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:37:51 |

US3532281

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'un UNK 1994' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:37:51 |

US3532281

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:37:51 |

US3532281

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:09:56

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:37:51 |

US3532281

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'un UNK 1994' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:37:51 |

US3532281

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:09:56

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:37:51 |

US3532281

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:09:56

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'Jan 1994' | System | 11 Sep 2020 13:37:51 |

US3532281

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:09:56

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '1994' | System | 11 Sep 2020 13:37:51 |

US3532281

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'Jan 1994' | System | 11 Sep 2020 13:37:51 |

US3532281

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '1994' | System | 11 Sep 2020 13:37:51 |

US3532281

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:09:56

[Condition](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Sep 2020 13:40:36 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Sep 2020 13:40:36 |
| Data point term sent to Coder | System | 11 Sep 2020 13:39:13 |
| User entered 'Osteoarthritis' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:38:28 |

US3532281

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'un UNK 2005' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:38:28 |

US3532281

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:38:28 |

US3532281

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:09:56

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:38:28 |

US3532281

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:38:28 |

US3532281

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:09:56

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:38:28 |

US3532281

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:09:56

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'Jan 2005' | System | 11 Sep 2020 13:38:28 |

US3532281

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:09:56

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '2005' | System | 11 Sep 2020 13:38:28 |

US3532281

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered empty. | System | 11 Sep 2020 13:38:28 |

US3532281

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered empty. | System | 11 Sep 2020 13:38:28 |

US3532281

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:09:56

[Condition](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| 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) | 11 Sep 2020 13:40:35 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Sep 2020 13:40:35 |
| Data point term sent to Coder | System | 11 Sep 2020 13:39:16 |
| User entered 'Hearing loss' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:38:45 |

US3532281

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'un UNK 2014' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:38:45 |

US3532281

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:38:45 |

US3532281

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:09:56

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:38:45 |

US3532281

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:38:45 |

US3532281

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:09:56

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:38:45 |

US3532281

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:09:56

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'Jan 2014' | System | 11 Sep 2020 13:38:45 |

US3532281

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:09:56

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '2014' | System | 11 Sep 2020 13:38:45 |

US3532281

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered empty. | System | 11 Sep 2020 13:38:45 |

US3532281

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered empty. | System | 11 Sep 2020 13:38:45 |

US3532281

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:09:56

[Condition](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit/hyperactivity disorder - version MedDRA\\23.0. | Coder Import (b) (4) | 31 Mar 2021 21:20:02 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 31 Mar 2021 21:20:02 |
| Data point term sent to Coder | System | 31 Mar 2021 21:18:57 |
| User entered 'Attention deficit hyperactivity disorder' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:18:01 |

US3532281

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'un UNK 2012' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:18:01 |

US3532281

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '0' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:18:01 |

US3532281

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:09:56

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:18:01 |

US3532281

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered empty. | Cindy Lubbers (b) (4) | 31 Mar 2021 21:18:01 |

US3532281

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:09:56

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '0' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:18:01 |

US3532281

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'Jan 2012' | System | 31 Mar 2021 21:18:01 |

US3532281

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '2012' | System | 31 Mar 2021 21:18:01 |

US3532281

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered empty. | System | 31 Mar 2021 21:18:01 |

US3532281

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered empty. | System | 31 Mar 2021 21:18:01 |

US3532281

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:09:56

[Condition](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0. | Coder Import (b) (4) | 31 Mar 2021 21:21:04 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 31 Mar 2021 21:21:04 |
| Data point term sent to Coder | System | 31 Mar 2021 21:19:58 |
| User entered 'Season allergies' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:19:09 |

US3532281

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'un UNK 2019' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:19:09 |

US3532281

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '0' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:19:09 |

US3532281

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:09:56

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:19:09 |

US3532281

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered empty. | Cindy Lubbers (b) (4) | 31 Mar 2021 21:19:09 |

US3532281

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:09:56

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '0' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:19:09 |

US3532281

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:09:56

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'Jan 2019' | System | 31 Mar 2021 21:19:09 |

US3532281

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:09:56

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '2019' | System | 31 Mar 2021 21:19:09 |

US3532281

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered empty. | System | 31 Mar 2021 21:19:09 |

US3532281

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered empty. | System | 31 Mar 2021 21:19:09 |

US3532281

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:09:56

[Condition](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Dermal filler injection, LLT: Dermal filler injection - version MedDRA\\23.0. | Coder Import (b) (4) | 31 Mar 2021 21:23:05 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 31 Mar 2021 21:23:05 |
| Data point term sent to Coder | System | 31 Mar 2021 21:21:59 |
| User entered 'Dermal filler injection' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:21:33 |

US3532281

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'un UNK 2015' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:21:33 |

US3532281

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '0' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:21:33 |

US3532281

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:09:56

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:21:33 |

US3532281

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'un UNK 2015' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:21:33 |

US3532281

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:09:56

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '0' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:21:33 |

US3532281

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:09:56

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'Jan 2015' | System | 31 Mar 2021 21:21:33 |

US3532281

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '2015' | System | 31 Mar 2021 21:21:33 |

US3532281

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'Jan 2015' | System | 31 Mar 2021 21:21:33 |

US3532281

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '2015' | System | 31 Mar 2021 21:21:33 |

US3532281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:46:31 |

US3532281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '10 Sep 2020' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:46:31 |

US3532281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '13:20' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:46:31 |

US3532281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '10 Sep 2020 13:20' | System | 11 Sep 2020 13:46:31 |

US3532281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

Height (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '174' cm | (b) (4) Cindy Lubbers (b) (4) | 11 Sep 2020 13:46:31 |
| DataPoint set to visible. | (b) (4) System | 10 Sep 2020 18:52:34 |

US3532281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

Weight (xxx.x)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User closed query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System). | (b) (4) | 06 Oct 2020 19:45:19 |
| Query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' answered by data change (Site from System). | System | 06 Oct 2020 19:45:19 |
| User entered '77' kg reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 06 Oct 2020 19:45:19 |
| Amendment Manager: User opened query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System). | (b) (4) | |
| User entered '25.4' kg | System | 17 Sep 2020 00:32:29 |
| DataPoint set to visible. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:46:31 |
| | (b) (4) | |
| | System | 10 Sep 2020 18:52:34 |

US3532281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '25.43269' | System | 06 Oct 2020 19:45:19 |
| User entered '8.38948' | System | 11 Sep 2020 13:46:31 |
| DataPoint set to visible. | System | 10 Sep 2020 18:52:34 |

US3532281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'kg/m2' | System | 11 Sep 2020 13:46:31 |
| DataPoint set to visible. | System | 10 Sep 2020 18:52:34 |

US3532281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered missing code ND - Not Done. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:46:31 |

US3532281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:46:31 |

US3532281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:46:31 |

US3532281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered missing code ND - Not Done. | (b) (4) Cindy Lubbers (b) (4) | 11 Sep 2020 13:46:31 |

US3532281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'bpm' | System | 11 Sep 2020 13:46:31 |

US3532281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered missing code ND - Not Done. | (b) (4) Cindy Lubbers (b) (4) | 11 Sep 2020 13:46:31 |

US3532281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'breaths/min' | System | 11 Sep 2020 13:46:31 |

US3532281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered missing code ND - Not Done. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:46:31 |

US3532281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'mmHg' | System | 11 Sep 2020 13:46:31 |

US3532281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered missing code ND - Not Done. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:46:31 |

US3532281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'mmHg' | System | 11 Sep 2020 13:46:31 |

US3532281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| | | |

US3532281

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| | | |

US3532281

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:56

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:52:47 |

US3532281

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:56

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '10 Sep 2020' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:52:47 |

US3532281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:56

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:54:00 |

US3532281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:56

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'No (N)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 10 Sep 2020 18:54:00 |

US3532281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:56

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) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:54:00 |

US3532281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:56

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) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:54:00 |

US3532281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:56

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:54:00 |

US3532281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:56

[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) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:54:00 |

US3532281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:56

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) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:54:00 |

US3532281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:56

[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) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:54:00 |

US3532281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:56

[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) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:54:00 |

US3532281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:56

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) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:54:00 |

US3532281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:56

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) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:54:00 |

US3532281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:56

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:54:00 |

US3532281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:56

[Specify](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Landscaping business daily multiple person contact' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:54:00 |

US3532281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:56

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:54:00 |

US3532281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:56

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:54:00 |

US3532281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:56

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) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:54:00 |

US3532281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:56

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) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:54:00 |

US3532281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:56

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) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:54:00 |

US3532281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:56

[Resides in a single family home](#) (i.e., detached housing)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'I' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:54:00 |

US3532281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:56

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '0' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:54:00 |

US3532281

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:56

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered empty. | (b) (4) Cindy Lubbers (b) (4) | 10 Sep 2020 18:54:00 |

US3532281

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:09:56

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 10 Sep 2020 17:51:23 |

US3532281

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '10 Sep 2020' | Cindy Lubbers (b) (4) | 10 Sep 2020 17:51:23 |

US3532281

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Clinic (Clinic)' | Cindy Lubbers (b) (4) | 10 Sep 2020 17:51:23 |

US3532281

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:09:56

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User entered 'VISIT1' | System | 10 Sep 2020 17:51:23 |

US3532281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '10 SEP 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 10 Sep 2020 18:19:32 |

US3532281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:56

[What was the participant's randomization number?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '190539' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 10 Sep 2020 18:19:32 |

US3532281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:56

[In what Cohort was the participant enrolled?](#)

| Audit | User | Time (GMT) |
|-------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '>=65 years (3)' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 10 Sep 2020 18:19:32 |

US3532281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:56

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) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 10 Sep 2020 17:51:36 |

US3532281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:56

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) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 10 Sep 2020 17:51:36 |

US3532281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:56

Severe obesity (body mass index > or = 40kg/m2

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 10 Sep 2020 17:51:36 |

US3532281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:56

Diabetes (Type I, Type 2, or gestational)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 10 Sep 2020 17:51:36 |

US3532281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:56

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 10 Sep 2020 17:51:36 |

US3532281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:56

[Human Immunodeficiency Virus \(HIV\) infection](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'No (N)' | Etza Peters (b) (4) | 25 Sep 2020 16:32:36 |
| Amendment Manager: DataPoint set to visible. | System | 19 Sep 2020 06:01:13 |
| Amendment Manager inserted this DataPoint. | System | 19 Sep 2020 06:01:11 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:56

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered missing code ND - Not Done. | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:56

Weight

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered missing code ND - Not Done. | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:56

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered missing code ND - Not Done. | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:56

Weight

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered missing code ND - Not Done. | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Cindy Lubbers (b) (4) (b) (4) | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '10 Sep 2020' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System). | (b) (4) System | 18 Sep 2020 17:15:11 |
| User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System). | System | 10 Sep 2020 18:56:35 |
| User entered '13:20' | Cindy Lubbers (b) (4) (b) (4) | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User entered '10 Sep 2020 13:20' | System | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '97.3' F | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Oral (Oral)' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered empty. | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '66' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User entered 'bpm' | System | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '16' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User entered 'breaths/min' | System | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '144' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User entered 'mmHg' | System | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '90' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User entered 'mmHg' | System | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:56

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered missing code ND - Not Done. | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:56

Weight

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered missing code ND - Not Done. | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Cindy Lubbers (b) (4) (b) (4) | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '10 Sep 2020' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 18 Sep 2020 17:14:18 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 18 Sep 2020 17:14:18 |
| User entered '15:13' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 18 Sep 2020 17:14:18 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 10 Sep 2020 18:55:31 |
| User entered empty. | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:31 |
| | (b) (4) | |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User entered '10 Sep 2020 15:13' | System | 18 Sep 2020 17:14:18 |
| User entered empty. | System | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 18 Sep 2020 17:14:18 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 18 Sep 2020 17:14:18 |
| User entered '97.0' F reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 18 Sep 2020 17:14:18 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 10 Sep 2020 18:55:31 |
| User entered empty. | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:31 |
| | (b) (4) | |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 18 Sep 2020 17:14:18 |
| User entered empty. | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered empty. | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 18 Sep 2020 17:14:18 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 18 Sep 2020 17:14:18 |
| User entered '64' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 18 Sep 2020 17:14:18 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | 10 Sep 2020 18:55:31 |
| User entered empty. | System | 10 Sep 2020 18:55:31 |
| | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:31 |
| | (b) (4) | |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User entered 'bpm' | System | 18 Sep 2020 17:14:18 |
| User entered empty. | System | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 18 Sep 2020 17:14:18 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 18 Sep 2020 17:14:18 |
| User entered '18' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 18 Sep 2020 17:14:18 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 10 Sep 2020 18:55:31 |
| User entered empty. | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:31 |
| | (b) (4) | |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User entered 'breaths/min' | System | 18 Sep 2020 17:14:18 |
| User entered empty. | System | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 18 Sep 2020 17:14:18 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 18 Sep 2020 17:14:18 |
| User entered '142' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 18 Sep 2020 17:14:18 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 10 Sep 2020 18:55:31 |
| User entered empty. | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:31 |
| | (b) (4) | |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User entered 'mmHg' | System | 18 Sep 2020 17:14:18 |
| User entered empty. | System | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 18 Sep 2020 17:14:18 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 18 Sep 2020 17:14:18 |
| User entered '90' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 18 Sep 2020 17:14:18 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 10 Sep 2020 18:55:31 |
| User entered empty. | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:31 |
| | (b) (4) | |

US3532281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User entered 'mmHg' | System | 18 Sep 2020 17:14:18 |
| User entered empty. | System | 10 Sep 2020 18:55:31 |

US3532281

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:56

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:41 |

US3532281

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:56

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '10 Sep 2020' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:55:41 |

US3532281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:56

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:56:35 |

US3532281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:56

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered empty. | Cindy Lubbers (b) (4) | 10 Sep 2020 18:56:35 |

US3532281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:56

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) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered empty. | Cindy Lubbers (b) (4) | 10 Sep 2020 18:56:35 |

US3532281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:56

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:56

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '10 Sep 2020' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:56:35 |

US3532281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:56

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '14:38' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 18 Sep 2020 17:15:11 |
| User entered '13:20' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:56:35 |

US3532281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:56

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User entered '10 Sep 2020 14:38' | System | 18 Sep 2020 17:15:11 |
| User entered '10 Sep 2020 13:20' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:56

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Left Arm (LEFT ARM)' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:56:35 |

US3532281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:56

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User entered 'ONCE' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:56

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User entered 'INTRAMUSCULAR' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:56

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:56:55 |

US3532281

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:56

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '10 Sep 2020' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:56:55 |

US3532281

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:56

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '14:20' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:56:55 |

US3532281

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:56

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User entered '10 Sep 2020 14:20' | System | 10 Sep 2020 18:56:55 |

US3532281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:09:56

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System). | (b) (4) | 10 Sep 2020 18:57:46 |
| Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System). | System | 10 Sep 2020 18:57:46 |
| User entered '10 Sep 2020' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 10 Sep 2020 18:57:46 |
| User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System). | (b) (4) | 10 Sep 2020 18:57:38 |
| User entered empty. | System | 10 Sep 2020 18:57:38 |
| | Cindy Lubbers (b) (4) | 10 Sep 2020 18:57:38 |
| | (b) (4) | |

US3532281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:09:56

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Cindy Lubbers (b) (4) (b) (4) | 10 Sep 2020 18:57:38 |

US3532281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:09:56

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:57:38 |

US3532281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:09:56

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '14:03' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:57:38 |

US3532281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:09:56

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User entered '10 Sep 2020 14:03' | System | 10 Sep 2020 18:57:46 |
| User entered empty. | System | 10 Sep 2020 18:57:38 |

US3532281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:09:56

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Cindy Lubbers (b) (4) (b) (4) | 10 Sep 2020 18:57:38 |

US3532281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:09:56

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:57:38 |

US3532281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:09:56

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered empty. | Cindy Lubbers (b) (4) | 10 Sep 2020 18:57:38 |

US3532281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:09:56

Collection date and time (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User entered empty. | System | 10 Sep 2020 18:57:38 |

US3532281

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 10 Sep 2020 18:57:58 |

US3532281

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User entered '1' | System | 10 Sep 2020 18:57:58 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T15:15:13', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'd3af1c9b-8d56-44c9-957e-5fa84f270b8e' User entered 'Yes (Y)' | System | 10 Sep 2020 19:15:42 |
| | System | 10 Sep 2020 19:15:42 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T15:15:26', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'd3af1c9b-8d56-44c9-957e-5fa84f270b8e' User entered '97.0' | System | 10 Sep 2020 19:15:42 |
| | System | 10 Sep 2020 19:15:42 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T15:15:34', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'd3af1c9b-8d56-44c9-957e-5fa84f270b8e' | System | 10 Sep 2020 19:15:42 |
| User entered 'No (N)' | System | 10 Sep 2020 19:15:42 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T15:15:40', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'd3af1c9b-8d56-44c9-957e-5fa84f270b8e' User entered '10 Sep 2020 15:15' | System | 10 Sep 2020 19:15:42 |
| | System | 10 Sep 2020 19:15:42 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '10 Sep 2020 13:40' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '10 Sep 2020 16:10' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 1, after vaccination (at home)' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T22:38:21', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '26a57e92-54ee-44b4-8813-3a85dffc6d71' User entered 'Yes (Y)' | System | 11 Sep 2020 02:38:50 |
| | System | 11 Sep 2020 02:38:50 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T22:38:36', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '26a57e92-54ee-44b4-8813-3a85dff6d71' User entered '97.5' | System | 11 Sep 2020 02:38:50 |
| | System | 11 Sep 2020 02:38:50 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T22:38:42', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '26a57e92-54ee-44b4-8813-3a85dffc6d71' User entered 'No (N)' | System | 11 Sep 2020 02:38:50 |
| | System | 11 Sep 2020 02:38:50 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T22:38:48', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '26a57e92-54ee-44b4-8813-3a85dffc6d71' User entered '10 Sep 2020 22:38' | System | 11 Sep 2020 02:38:50 |
| | System | 11 Sep 2020 02:38:50 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '10 Sep 2020 17:05' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '11 Sep 2020 11:59' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 2' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:56

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-11T21:37:23', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'ea364b42-0689-4173-adcf-8f5a1e984fa3' User entered 'Yes (Y)' | System | 12 Sep 2020 01:37:58 |
| | System | 12 Sep 2020 01:37:58 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:56

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-11T21:37:33', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'ea364b42-0689-4173-adcf-8f5a1e984fa3' User entered '98.3' | System | 12 Sep 2020 01:37:58 |
| | System | 12 Sep 2020 01:37:58 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-11T21:37:39', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'ea364b42-0689-4173-adcf-8f5a1e984fa3' | System | 12 Sep 2020 01:37:58 |
| User entered 'No (N)' | System | 12 Sep 2020 01:37:58 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-11T21:37:51', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'ea364b42-0689-4173-adcf-8f5a1e984fa3' | System | 12 Sep 2020 01:37:58 |
| User entered '11 Sep 2020 21:37' | System | 12 Sep 2020 01:37:58 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '11 Sep 2020 12:00' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '12 Sep 2020 11:59' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 3' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:56

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-12T22:34:22', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '8537d3ff-1cf4-4ca5-9430-a0b80caae6fe' User entered 'Yes (Y)' | System | 13 Sep 2020 02:35:26 |
| | System | 13 Sep 2020 02:35:26 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:56

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-12T22:34:29', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '8537d3ff-1cf4-4ca5-9430-a0b80caae6fe' User entered '97.5' | System | 13 Sep 2020 02:35:26 |
| | System | 13 Sep 2020 02:35:26 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-12T22:34:36', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '8537d3ff-1cf4-4ca5-9430-a0b80caae6fe' | System | 13 Sep 2020 02:35:26 |
| User entered 'No (N)' | System | 13 Sep 2020 02:35:26 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-12T22:34:41', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '8537d3ff-1cf4-4ca5-9430-a0b80caae6fe' User entered '12 Sep 2020 22:34' | System | 13 Sep 2020 02:35:26 |
| | System | 13 Sep 2020 02:35:26 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '12 Sep 2020 12:00' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '13 Sep 2020 11:59' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 4' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:56

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-13T20:34:27', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'c5aa719b-b920-4752-b745-4fbb65d8f0e3' User entered 'Yes (Y)' | System | 14 Sep 2020 00:34:53 |
| | System | 14 Sep 2020 00:34:53 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:56

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-13T20:34:33', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'c5aa719b-b920-4752-b745-4fbb65d8f0e3' User entered '98.4' | System | 14 Sep 2020 00:34:53 |
| | System | 14 Sep 2020 00:34:53 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-13T20:34:39', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'c5aa719b-b920-4752-b745-4fbb65d8f0e3' | System | 14 Sep 2020 00:34:53 |
| User entered 'No (N)' | System | 14 Sep 2020 00:34:53 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-13T20:34:47', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'c5aa719b-b920-4752-b745-4fbb65d8f0e3' User entered '13 Sep 2020 20:34' | System | 14 Sep 2020 00:34:53 |
| | System | 14 Sep 2020 00:34:53 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '13 Sep 2020 12:00' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '14 Sep 2020 11:59' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 5' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:56

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-14T22:39:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'e03be517-f277-4244-9d15-87d103a83838' User entered 'Yes (Y)' | System | 15 Sep 2020 02:39:23 |
| | System | 15 Sep 2020 02:39:23 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:56

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-14T22:39:08', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'e03be517-f277-4244-9d15-87d103a83838' User entered '98.5' | System | 15 Sep 2020 02:39:23 |
| | System | 15 Sep 2020 02:39:23 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-14T22:39:13', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'e03be517-f277-4244-9d15-87d103a83838' | System | 15 Sep 2020 02:39:23 |
| User entered 'No (N)' | System | 15 Sep 2020 02:39:23 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-14T22:39:21', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'e03be517-f277-4244-9d15-87d103a83838' | System | 15 Sep 2020 02:39:23 |
| User entered '14 Sep 2020 22:39' | System | 15 Sep 2020 02:39:23 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '14 Sep 2020 12:00' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '15 Sep 2020 11:59' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 6' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:56

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-15T19:15:43', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '7e970de8-3ab2-4c8a-b2b3-1d6c5ebdc525' User entered 'Yes (Y)' | System | 15 Sep 2020 23:16:01 |
| | System | 15 Sep 2020 23:16:01 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:56

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-15T19:15:49', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '7e970de8-3ab2-4c8a-b2b3-1d6c5ebdc525' User entered '98.3' | System | 15 Sep 2020 23:16:01 |
| | System | 15 Sep 2020 23:16:01 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-15T19:15:54', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '7e970de8-3ab2-4c8a-b2b3-1d6c5ebdc525' | System | 15 Sep 2020 23:16:01 |
| User entered 'No (N)' | System | 15 Sep 2020 23:16:01 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-15T19:15:58', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '7e970de8-3ab2-4c8a-b2b3-1d6c5ebdc525' | System | 15 Sep 2020 23:16:01 |
| User entered '15 Sep 2020 19:15' | System | 15 Sep 2020 23:16:01 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '15 Sep 2020 12:00' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '16 Sep 2020 11:59' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 7' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:56

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-17T09:35:30', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '4ab4ed44-10cb-442c-b191-a09ebb2512d4' User entered 'Yes (Y)' | System | 17 Sep 2020 13:35:51 |
| | System | 17 Sep 2020 13:35:51 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:56

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-17T09:35:35', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '4ab4ed44-10cb-442c-b191-a09ebb2512d4' User entered '97.9' | System | 17 Sep 2020 13:35:51 |
| | System | 17 Sep 2020 13:35:51 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-17T09:35:40', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '4ab4ed44-10cb-442c-b191-a09ebb2512d4' | System | 17 Sep 2020 13:35:51 |
| User entered 'No (N)' | System | 17 Sep 2020 13:35:51 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-17T09:35:48', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '4ab4ed44-10cb-442c-b191-a09ebb2512d4' User entered '17 Sep 2020 09:35' | System | 17 Sep 2020 13:35:51 |
| | System | 17 Sep 2020 13:35:51 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '16 Sep 2020 12:00' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '17 Sep 2020 11:59' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T15:16:01', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '2b84f62f-c1dc-4c42-bffd-bf9a0cec20aa' | System | 10 Sep 2020 19:16:28 |
| User entered 'None (1)' | System | 10 Sep 2020 19:16:28 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T15:16:04', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '2b84f62f-c1dc-4c42-bffd-bf9a0cec20aa' | System | 10 Sep 2020 19:16:28 |
| User entered 'No (N)' | System | 10 Sep 2020 19:16:28 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T15:16:07', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '2b84f62f-c1dc-4c42-bffd-bf9a0cec20aa' | System | 10 Sep 2020 19:16:28 |
| User entered 'No (N)' | System | 10 Sep 2020 19:16:28 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T15:16:20', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '2b84f62f-c1dc-4c42-bffd-bf9a0cec20aa' User entered 'None (1)' | System | 10 Sep 2020 19:16:28 |
| | System | 10 Sep 2020 19:16:28 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T15:16:25', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '2b84f62f-c1dc-4c42-bffd-bf9a0cec20aa' | System | 10 Sep 2020 19:16:28 |
| User entered '10 Sep 2020 15:16' | System | 10 Sep 2020 19:16:28 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '10 Sep 2020 13:40' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '10 Sep 2020 16:10' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 1, after vaccination (at home)' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T22:38:59', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '3066c358-3a06-4423-91f9-26a09c6af0f5' | System | 11 Sep 2020 02:39:24 |
| User entered 'None (1)' | System | 11 Sep 2020 02:39:24 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T22:39:03', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '3066c358-3a06-4423-91f9-26a09c6af0f5' | System | 11 Sep 2020 02:39:24 |
| User entered 'No (N)' | System | 11 Sep 2020 02:39:24 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T22:39:06', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '3066c358-3a06-4423-91f9-26a09c6af0f5' | System | 11 Sep 2020 02:39:24 |
| User entered 'No (N)' | System | 11 Sep 2020 02:39:24 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T22:39:13', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '3066c358-3a06-4423-91f9-26a09c6af0f5' | System | 11 Sep 2020 02:39:24 |
| User entered 'None (1)' | System | 11 Sep 2020 02:39:24 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T22:39:23', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '3066c358-3a06-4423-91f9-26a09c6af0f5' | System | 11 Sep 2020 02:39:24 |
| User entered '10 Sep 2020 22:39' | System | 11 Sep 2020 02:39:24 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '10 Sep 2020 17:05' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '11 Sep 2020 11:59' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 2' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-11T21:38:17', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '09f56cd2-5fef-434f-a200-ab20b894b883' | System | 12 Sep 2020 01:38:42 |
| User entered 'Does not interfere with activity (2)' | System | 12 Sep 2020 01:38:42 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:56

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-11T21:38:21', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '09f56cd2-5fef-434f-a200-ab20b894b883' | System | 12 Sep 2020 01:38:42 |
| User entered 'No (N)' | System | 12 Sep 2020 01:38:42 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-11T21:38:28', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '09f56cd2-5fef-434f-a200-ab20b894b883' | System | 12 Sep 2020 01:38:42 |
| User entered 'No (N)' | System | 12 Sep 2020 01:38:42 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-11T21:38:33', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '09f56cd2-5fef-434f-a200-ab20b894b883' | System | 12 Sep 2020 01:38:42 |
| User entered 'None (1)' | System | 12 Sep 2020 01:38:42 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-11T21:38:36', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '09f56cd2-5fef-434f-a200-ab20b894b883' | System | 12 Sep 2020 01:38:42 |
| User entered '11 Sep 2020 21:38' | System | 12 Sep 2020 01:38:42 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '11 Sep 2020 12:00' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '12 Sep 2020 11:59' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 3' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-12T22:35:02', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'aff3fab3-145b-4742-97d7-2797e1b91fd4' | System | 13 Sep 2020 02:35:54 |
| User entered 'None (1)' | System | 13 Sep 2020 02:35:54 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:56

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-12T22:35:06', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'aff3fab3-145b-4742-97d7-2797e1b91fd4' | System | 13 Sep 2020 02:35:54 |
| User entered 'No (N)' | System | 13 Sep 2020 02:35:54 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-12T22:35:09', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'aff3fab3-145b-4742-97d7-2797e1b91fd4' | System | 13 Sep 2020 02:35:54 |
| User entered 'No (N)' | System | 13 Sep 2020 02:35:54 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-12T22:35:16', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'aff3fab3-145b-4742-97d7-2797e1b91fd4' User entered 'None (1)' | System | 13 Sep 2020 02:35:54 |
| | System | 13 Sep 2020 02:35:54 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-12T22:35:21', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'aff3fab3-145b-4742-97d7-2797e1b91fd4' | System | 13 Sep 2020 02:35:54 |
| User entered '12 Sep 2020 22:35' | System | 13 Sep 2020 02:35:54 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '12 Sep 2020 12:00' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '13 Sep 2020 11:59' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 4' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-13T20:34:54', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '8a241f44-eb81-436a-b3cd-2b2fc2745c9c' | System | 14 Sep 2020 00:35:18 |
| User entered 'None (1)' | System | 14 Sep 2020 00:35:18 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:56

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-13T20:34:58', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '8a241f44-eb81-436a-b3cd-2b2fc2745c9c' User entered 'No (N)' | System | 14 Sep 2020 00:35:18 |
| | System | 14 Sep 2020 00:35:18 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-13T20:35:03', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '8a241f44-eb81-436a-b3cd-2b2fc2745c9c' User entered 'No (N)' | System | 14 Sep 2020 00:35:18 |
| | System | 14 Sep 2020 00:35:18 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-13T20:35:12', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '8a241f44-eb81-436a-b3cd-2b2fc2745c9c' | System | 14 Sep 2020 00:35:18 |
| User entered 'None (1)' | System | 14 Sep 2020 00:35:18 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-13T20:35:15', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '8a241f44-eb81-436a-b3cd-2b2fc2745c9c' User entered '13 Sep 2020 20:35' | System | 14 Sep 2020 00:35:18 |
| | System | 14 Sep 2020 00:35:18 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '13 Sep 2020 12:00' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '14 Sep 2020 11:59' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 5' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-14T22:39:26', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '05a8e78b-de2e-42ec-814a-348fdbfbdc38' | System | 15 Sep 2020 02:39:52 |
| User entered 'None (1)' | System | 15 Sep 2020 02:39:52 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:56

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-14T22:39:30', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '05a8e78b-de2e-42ec-814a-348fdbfbdc38' | System | 15 Sep 2020 02:39:52 |
| User entered 'No (N)' | System | 15 Sep 2020 02:39:52 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-14T22:39:35', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '05a8e78b-de2e-42ec-814a-348fdbfbdc38' User entered 'No (N)' | System | 15 Sep 2020 02:39:52 |
| | System | 15 Sep 2020 02:39:52 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-14T22:39:45', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '05a8e78b-de2e-42ec-814a-348fdbfbdc38' User entered 'None (1)' | System | 15 Sep 2020 02:39:52 |
| | System | 15 Sep 2020 02:39:52 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-14T22:39:50', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '05a8e78b-de2e-42ec-814a-348fdbfbdc38' User entered '14 Sep 2020 22:39' | System | 15 Sep 2020 02:39:52 |
| | System | 15 Sep 2020 02:39:52 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '14 Sep 2020 12:00' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '15 Sep 2020 11:59' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 6' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-15T19:16:05', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '897b176a-8d66-40f7-857e-ac68908c4b77' | System | 15 Sep 2020 23:16:25 |
| User entered 'None (1)' | System | 15 Sep 2020 23:16:25 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:56

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-15T19:16:08', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '897b176a-8d66-40f7-857e-ac68908c4b77' | System | 15 Sep 2020 23:16:25 |
| User entered 'No (N)' | System | 15 Sep 2020 23:16:25 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-15T19:16:12', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '897b176a-8d66-40f7-857e-ac68908c4b77' | System | 15 Sep 2020 23:16:25 |
| User entered 'No (N)' | System | 15 Sep 2020 23:16:25 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-15T19:16:18', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '897b176a-8d66-40f7-857e-ac68908c4b77' | System | 15 Sep 2020 23:16:25 |
| User entered 'None (1)' | System | 15 Sep 2020 23:16:25 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-15T19:16:22', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '897b176a-8d66-40f7-857e-ac68908c4b77' | System | 15 Sep 2020 23:16:25 |
| User entered '15 Sep 2020 19:16' | System | 15 Sep 2020 23:16:25 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '15 Sep 2020 12:00' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '16 Sep 2020 11:59' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 7' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-17T09:35:54', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '76a4534d-ea8f-4f1e-8ddd-ff11071b75e5' | System | 17 Sep 2020 13:36:21 |
| User entered 'None (1)' | System | 17 Sep 2020 13:36:21 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:56

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-17T09:35:58', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '76a4534d-ea8f-4f1e-8ddd-ff11071b75e5' User entered 'No (N)' | System | 17 Sep 2020 13:36:21 |
| | System | 17 Sep 2020 13:36:21 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-17T09:36:02', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '76a4534d-ea8f-4f1e-8ddd-ff11071b75e5' User entered 'No (N)' | System | 17 Sep 2020 13:36:21 |
| | System | 17 Sep 2020 13:36:21 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-17T09:36:06', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '76a4534d-ea8f-4f1e-8ddd-ff11071b75e5' | System | 17 Sep 2020 13:36:21 |
| User entered 'None (1)' | System | 17 Sep 2020 13:36:21 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-17T09:36:16', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '76a4534d-ea8f-4f1e-8ddd-ff11071b75e5' User entered '17 Sep 2020 09:36' | System | 17 Sep 2020 13:36:21 |
| | System | 17 Sep 2020 13:36:21 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '16 Sep 2020 12:00' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '17 Sep 2020 11:59' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T15:16:31', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '1099b92f-0d38-4b28-b41e-d8422e7b98c5' User entered 'None (0)' | System | 10 Sep 2020 19:17:07 |
| | System | 10 Sep 2020 19:17:07 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T15:16:39', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '1099b92f-0d38-4b28-b41e-d8422e7b98c5' User entered 'None (0)' | System | 10 Sep 2020 19:17:07 |
| | System | 10 Sep 2020 19:17:07 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T15:16:42', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '1099b92f-0d38-4b28-b41e-d8422e7b98c5' User entered 'None (0)' | System | 10 Sep 2020 19:17:07 |
| | System | 10 Sep 2020 19:17:07 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T15:16:45', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '1099b92f-0d38-4b28-b41e-d8422e7b98c5' User entered 'None (0)' | System | 10 Sep 2020 19:17:07 |
| | System | 10 Sep 2020 19:17:07 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T15:16:47', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '1099b92f-0d38-4b28-b41e-d8422e7b98c5' User entered 'None (0)' | System | 10 Sep 2020 19:17:07 |
| | System | 10 Sep 2020 19:17:07 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T15:16:49', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '1099b92f-0d38-4b28-b41e-d8422e7b98c5' User entered 'None (0)' | System | 10 Sep 2020 19:17:07 |
| | System | 10 Sep 2020 19:17:07 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T15:16:59', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '1099b92f-0d38-4b28-b41e-d8422e7b98c5' | System | 10 Sep 2020 19:17:07 |
| User entered 'No (N)' | System | 10 Sep 2020 19:17:07 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T15:17:02', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '1099b92f-0d38-4b28-b41e-d8422e7b98c5' User entered '10 Sep 2020 15:17' | System | 10 Sep 2020 19:17:07 |
| | System | 10 Sep 2020 19:17:07 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '10 Sep 2020 13:40' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '10 Sep 2020 16:10' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 1, after vaccination (at home)' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T22:39:55', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '4b04d7a4-6896-4593-831a-cfd89c5ccced' User entered 'None (0)' | System | 11 Sep 2020 02:40:26 |
| | System | 11 Sep 2020 02:40:26 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T22:39:58', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '4b04d7a4-6896-4593-831a-cfd89c5ccced' User entered 'None (0)' | System | 11 Sep 2020 02:40:26 |
| | System | 11 Sep 2020 02:40:26 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T22:40:01', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '4b04d7a4-6896-4593-831a-cfd89c5ccced' User entered 'None (0)' | System | 11 Sep 2020 02:40:26 |
| | System | 11 Sep 2020 02:40:26 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T22:40:06', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '4b04d7a4-6896-4593-831a-cfd89c5cccd' User entered 'None (0)' | System | 11 Sep 2020 02:40:26 |
| | System | 11 Sep 2020 02:40:26 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T22:40:07', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '4b04d7a4-6896-4593-831a-cfd89c5ccced' User entered 'None (0)' | System | 11 Sep 2020 02:40:26 |
| | System | 11 Sep 2020 02:40:26 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T22:40:09', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '4b04d7a4-6896-4593-831a-cfd89c5ccced' User entered 'None (0)' | System | 11 Sep 2020 02:40:26 |
| | System | 11 Sep 2020 02:40:26 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T22:40:15', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '4b04d7a4-6896-4593-831a-cfd89c5cccd' User entered 'No (N)' | System | 11 Sep 2020 02:40:26 |
| | System | 11 Sep 2020 02:40:26 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-10T22:40:23', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '4b04d7a4-6896-4593-831a-cfd89c5ccced' User entered '10 Sep 2020 22:40' | System | 11 Sep 2020 02:40:26 |
| | System | 11 Sep 2020 02:40:26 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '10 Sep 2020 17:05' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '11 Sep 2020 11:59' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 2' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-11T21:38:47', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '952e97c0-bebb-47d3-8ac8-d961fc9dce5e' User entered 'None (0)' | System | 12 Sep 2020 01:39:50 |
| | System | 12 Sep 2020 01:39:50 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-11T21:39:44', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '952e97c0-bebb-47d3-8ac8-d961fc9dce5e' | System | 12 Sep 2020 01:39:50 |
| User entered 'Some interference with activity (2)' | System | 12 Sep 2020 01:39:50 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-11T21:38:59', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '952e97c0-bebb-47d3-8ac8-d961fc9dce5e' User entered 'None (0)' | System | 12 Sep 2020 01:39:50 |
| | System | 12 Sep 2020 01:39:50 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-11T21:39:02', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '952e97c0-bebb-47d3-8ac8-d961fc9dce5e' User entered 'None (0)' | System | 12 Sep 2020 01:39:50 |
| | System | 12 Sep 2020 01:39:50 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-11T21:39:05', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '952e97c0-bebb-47d3-8ac8-d961fc9dce5e' User entered 'None (0)' | System | 12 Sep 2020 01:39:50 |
| | System | 12 Sep 2020 01:39:50 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-11T21:39:07', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '952e97c0-bebb-47d3-8ac8-d961fc9dce5e' User entered 'None (0)' | System | 12 Sep 2020 01:39:50 |
| | System | 12 Sep 2020 01:39:50 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-11T21:39:13', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '952e97c0-bebb-47d3-8ac8-d961fc9dce5e' User entered 'No (N)' | System | 12 Sep 2020 01:39:50 |
| | System | 12 Sep 2020 01:39:50 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-11T21:39:48', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '952e97c0-bebb-47d3-8ac8-d961fc9dce5e' User entered '11 Sep 2020 21:39' | System | 12 Sep 2020 01:39:50 |
| | System | 12 Sep 2020 01:39:50 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '11 Sep 2020 12:00' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '12 Sep 2020 11:59' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 3' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-12T22:35:30', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'feb7d58d-586a-41a8-a8f6-90cdd10c4bf3' User entered 'None (0)' | System | 13 Sep 2020 02:36:13 |
| | System | 13 Sep 2020 02:36:13 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-12T22:35:39', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'feb7d58d-586a-41a8-a8f6-90cdd10c4bf3' | System | 13 Sep 2020 02:36:13 |
| User entered 'No interference with activity (1)' | System | 13 Sep 2020 02:36:13 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-12T22:35:43', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'feb7d58d-586a-41a8-a8f6-90cdd10c4bf3' User entered 'None (0)' | System | 13 Sep 2020 02:36:13 |
| | System | 13 Sep 2020 02:36:13 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-12T22:35:46', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'feb7d58d-586a-41a8-a8f6-90cdd10c4bf3' User entered 'None (0)' | System | 13 Sep 2020 02:36:13 |
| | System | 13 Sep 2020 02:36:13 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-12T22:35:49', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'feb7d58d-586a-41a8-a8f6-90cdd10c4bf3' User entered 'None (0)' | System | 13 Sep 2020 02:36:13 |
| | System | 13 Sep 2020 02:36:13 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-12T22:35:51', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'feb7d58d-586a-41a8-a8f6-90cdd10c4bf3' User entered 'None (0)' | System | 13 Sep 2020 02:36:13 |
| | System | 13 Sep 2020 02:36:13 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-12T22:36:01', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'feb7d58d-586a-41a8-a8f6-90cdd10c4bf3' | System | 13 Sep 2020 02:36:13 |
| User entered 'No (N)' | System | 13 Sep 2020 02:36:13 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-12T22:36:07', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'feb7d58d-586a-41a8-a8f6-90cdd10c4bf3' | System | 13 Sep 2020 02:36:13 |
| User entered '12 Sep 2020 22:36' | System | 13 Sep 2020 02:36:13 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '12 Sep 2020 12:00' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '13 Sep 2020 11:59' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 4' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-13T20:35:28', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '71a4d443-7381-4813-97a9-1469d64964f0' User entered 'None (0)' | System | 14 Sep 2020 00:36:01 |
| | System | 14 Sep 2020 00:36:01 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-13T20:35:30', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '71a4d443-7381-4813-97a9-1469d64964f0' User entered 'None (0)' | System | 14 Sep 2020 00:36:01 |
| | System | 14 Sep 2020 00:36:01 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-13T20:35:33', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '71a4d443-7381-4813-97a9-1469d64964f0' User entered 'None (0)' | System | 14 Sep 2020 00:36:01 |
| | System | 14 Sep 2020 00:36:01 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-13T20:35:37', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '71a4d443-7381-4813-97a9-1469d64964f0' User entered 'None (0)' | System | 14 Sep 2020 00:36:01 |
| | System | 14 Sep 2020 00:36:01 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-13T20:35:39', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '71a4d443-7381-4813-97a9-1469d64964f0' User entered 'None (0)' | System | 14 Sep 2020 00:36:01 |
| | System | 14 Sep 2020 00:36:01 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-13T20:35:42', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '71a4d443-7381-4813-97a9-1469d64964f0' User entered 'None (0)' | System | 14 Sep 2020 00:36:01 |
| | System | 14 Sep 2020 00:36:01 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-13T20:35:48', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '71a4d443-7381-4813-97a9-1469d64964f0' | System | 14 Sep 2020 00:36:01 |
| User entered 'No (N)' | System | 14 Sep 2020 00:36:01 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-13T20:35:53', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '71a4d443-7381-4813-97a9-1469d64964f0' User entered '13 Sep 2020 20:35' | System | 14 Sep 2020 00:36:01 |
| | System | 14 Sep 2020 00:36:01 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '13 Sep 2020 12:00' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '14 Sep 2020 11:59' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 5' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-14T22:40:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '0b93795b-6483-412f-804a-9482ba4693e3' User entered 'None (0)' | System | 15 Sep 2020 02:40:27 |
| | System | 15 Sep 2020 02:40:27 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-14T22:40:03', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '0b93795b-6483-412f-804a-9482ba4693e3' User entered 'None (0)' | System | 15 Sep 2020 02:40:27 |
| | System | 15 Sep 2020 02:40:27 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-14T22:40:05', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '0b93795b-6483-412f-804a-9482ba4693e3' User entered 'None (0)' | System | 15 Sep 2020 02:40:27 |
| | System | 15 Sep 2020 02:40:27 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-14T22:40:09', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '0b93795b-6483-412f-804a-9482ba4693e3' User entered 'None (0)' | System | 15 Sep 2020 02:40:27 |
| | System | 15 Sep 2020 02:40:27 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-14T22:40:11', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '0b93795b-6483-412f-804a-9482ba4693e3' User entered 'None (0)' | System | 15 Sep 2020 02:40:27 |
| | System | 15 Sep 2020 02:40:27 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-14T22:40:14', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '0b93795b-6483-412f-804a-9482ba4693e3' User entered 'None (0)' | System | 15 Sep 2020 02:40:27 |
| | System | 15 Sep 2020 02:40:27 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-14T22:40:21', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '0b93795b-6483-412f-804a-9482ba4693e3' User entered 'No (N)' | System | 15 Sep 2020 02:40:27 |
| | System | 15 Sep 2020 02:40:27 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-14T22:40:24', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '0b93795b-6483-412f-804a-9482ba4693e3' User entered '14 Sep 2020 22:40' | System | 15 Sep 2020 02:40:27 |
| | System | 15 Sep 2020 02:40:27 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '14 Sep 2020 12:00' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '15 Sep 2020 11:59' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 6' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-15T19:16:34', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '8b3882bf-901f-415c-815a-9e815fcb2d43' User entered 'None (0)' | System | 15 Sep 2020 23:17:37 |
| | System | 15 Sep 2020 23:17:37 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-15T19:16:38', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '8b3882bf-901f-415c-815a-9e815fcb2d43' User entered 'None (0)' | System | 15 Sep 2020 23:17:37 |
| | System | 15 Sep 2020 23:17:37 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-15T19:16:44', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '8b3882bf-901f-415c-815a-9e815fcb2d43' User entered 'None (0)' | System | 15 Sep 2020 23:17:37 |
| | System | 15 Sep 2020 23:17:37 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-15T19:17:03', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '8b3882bf-901f-415c-815a-9e815fcb2d43' User entered 'None (0)' | System | 15 Sep 2020 23:17:37 |
| | System | 15 Sep 2020 23:17:37 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-15T19:17:09', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '8b3882bf-901f-415c-815a-9e815fcb2d43' User entered 'None (0)' | System | 15 Sep 2020 23:17:37 |
| | System | 15 Sep 2020 23:17:37 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-15T19:17:13', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '8b3882bf-901f-415c-815a-9e815fcb2d43' User entered 'None (0)' | System | 15 Sep 2020 23:17:37 |
| | System | 15 Sep 2020 23:17:37 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-15T19:17:29', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '8b3882bf-901f-415c-815a-9e815fcb2d43' | System | 15 Sep 2020 23:17:37 |
| User entered 'No (N)' | System | 15 Sep 2020 23:17:37 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-15T19:17:32', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '8b3882bf-901f-415c-815a-9e815fcb2d43' | System | 15 Sep 2020 23:17:37 |
| User entered '15 Sep 2020 19:17' | System | 15 Sep 2020 23:17:37 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '15 Sep 2020 12:00' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '16 Sep 2020 11:59' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 7' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-17T09:36:23', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'cb16996e-060e-4011-baed-195773f74c3f' User entered 'None (0)' | System | 17 Sep 2020 13:36:49 |
| | System | 17 Sep 2020 13:36:49 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-17T09:36:28', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'cb16996e-060e-4011-baed-195773f74c3f' User entered 'None (0)' | System | 17 Sep 2020 13:36:49 |
| | System | 17 Sep 2020 13:36:49 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-17T09:36:30', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'cb16996e-060e-4011-baed-195773f74c3f' User entered 'None (0)' | System | 17 Sep 2020 13:36:49 |
| | System | 17 Sep 2020 13:36:49 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-17T09:36:32', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'cb16996e-060e-4011-baed-195773f74c3f' User entered 'None (0)' | System | 17 Sep 2020 13:36:49 |
| | System | 17 Sep 2020 13:36:49 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-17T09:36:35', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'cb16996e-060e-4011-baed-195773f74c3f' User entered 'None (0)' | System | 17 Sep 2020 13:36:49 |
| | System | 17 Sep 2020 13:36:49 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-17T09:36:37', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'cb16996e-060e-4011-baed-195773f74c3f' User entered 'None (0)' | System | 17 Sep 2020 13:36:49 |
| | System | 17 Sep 2020 13:36:49 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-17T09:36:43', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'cb16996e-060e-4011-baed-195773f74c3f' User entered 'No (N)' | System | 17 Sep 2020 13:36:49 |
| | System | 17 Sep 2020 13:36:49 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-09-17T09:36:46', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'cb16996e-060e-4011-baed-195773f74c3f' User entered '17 Sep 2020 09:36' | System | 17 Sep 2020 13:36:49 |
| | System | 17 Sep 2020 13:36:49 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '16 Sep 2020 12:00' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '17 Sep 2020 11:59' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Yes (Y)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 18 Sep 2020 17:09:10 |

US3532281

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '18 Sep 2020' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 18 Sep 2020 17:09:10 |

US3532281

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 18 Sep 2020 17:09:10 |

US3532281

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered empty. | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 18 Sep 2020 17:09:10 |

US3532281

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 18 Sep 2020 17:09:14 |

US3532281

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered 'I' | System | 18 Sep 2020 17:09:14 |

US3532281

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Yes (Y)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 25 Sep 2020 21:31:13 |

US3532281

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '25 Sep 2020' | Cindy Lubbers (b) (4) | 25 Sep 2020 21:31:13 |

US3532281

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 25 Sep 2020 21:31:13 |

US3532281

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered empty. | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 25 Sep 2020 21:31:13 |

US3532281

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 25 Sep 2020 21:31:17 |

US3532281

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered 'I' | System | 25 Sep 2020 21:31:17 |

US3532281

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Yes (Y)' | (b) (4) Cindy Lubbers (b) (4) | 01 Oct 2020 20:30:10 |

US3532281

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '1 Oct 2020' | Cindy Lubbers (b) (4) | 01 Oct 2020 20:30:10 |

US3532281

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 01 Oct 2020 20:30:10 |

US3532281

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered empty. | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 01 Oct 2020 20:30:10 |

US3532281

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 01 Oct 2020 20:30:14 |

US3532281

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered 'I' | System | 01 Oct 2020 20:30:14 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:56

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 06 Oct 2020 19:45:49 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '6 Oct 2020' | Cindy Lubbers (b) (4) | 06 Oct 2020 19:45:49 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Clinic (Clinic)' | Cindy Lubbers (b) (4) | 06 Oct 2020 19:45:49 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:56

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered 'VISIT2' | System | 06 Oct 2020 19:45:49 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Cindy Lubbers (b) (4) (b) (4) | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '6 Oct 2020' | Cindy Lubbers (b) (4) | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '14:25' | Cindy Lubbers (b) (4) | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered '6 Oct 2020 14:25' | System | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '97.9' F | Cindy Lubbers (b) (4) | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Oral (Oral)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered empty. | Cindy Lubbers (b) (4) | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '71' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered 'bpm' | System | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '16' | Cindy Lubbers (b) (4) | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered 'breaths/min' | System | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '138' | Cindy Lubbers (b) (4) | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered 'mmHg' | System | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '77' | Cindy Lubbers (b) (4) | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:56

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered 'mmHg' | System | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Cindy Lubbers (b) (4) (b) (4) | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Yes (Y)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '6 Oct 2020' | Cindy Lubbers (b) (4) | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 06 Oct 2020 20:12:38 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 06 Oct 2020 20:12:38 |
| User entered '16:03' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 06 Oct 2020 20:12:38 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | 06 Oct 2020 19:47:52 |
| User entered empty. | System | 06 Oct 2020 19:47:52 |
| | Cindy Lubbers (b) (4) | 06 Oct 2020 19:47:52 |
| | (b) (4) | |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered '6 Oct 2020 16:03' | System | 06 Oct 2020 20:12:38 |
| User entered empty. | System | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 06 Oct 2020 20:12:38 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 06 Oct 2020 20:12:38 |
| User entered '98.5' F reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 06 Oct 2020 20:12:38 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | 06 Oct 2020 19:47:52 |
| User entered empty. | System | 06 Oct 2020 19:47:52 |
| | Cindy Lubbers (b) (4) | 06 Oct 2020 19:47:52 |
| | (b) (4) | |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Oral (Oral)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered empty. | Cindy Lubbers (b) (4) | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 06 Oct 2020 20:12:38 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 06 Oct 2020 20:12:38 |
| User entered '66' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 06 Oct 2020 20:12:38 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | 06 Oct 2020 19:47:52 |
| User entered empty. | System | 06 Oct 2020 19:47:52 |
| | Cindy Lubbers (b) (4) | 06 Oct 2020 19:47:52 |
| | (b) (4) | |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered 'bpm' | System | 06 Oct 2020 20:12:38 |
| User entered empty. | System | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 06 Oct 2020 20:12:38 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 06 Oct 2020 20:12:38 |
| User entered '16' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 06 Oct 2020 20:12:38 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | 06 Oct 2020 19:47:52 |
| User entered empty. | System | 06 Oct 2020 19:47:52 |
| | Cindy Lubbers (b) (4) | 06 Oct 2020 19:47:52 |
| | (b) (4) | |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered 'breaths/min' | System | 06 Oct 2020 20:12:38 |
| User entered empty. | System | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 06 Oct 2020 20:12:38 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 06 Oct 2020 20:12:38 |
| User entered '136' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 06 Oct 2020 20:12:38 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | 06 Oct 2020 19:47:52 |
| User entered empty. | System | 06 Oct 2020 19:47:52 |
| | Cindy Lubbers (b) (4) | 06 Oct 2020 19:47:52 |
| | (b) (4) | |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered 'mmHg' | System | 06 Oct 2020 20:12:38 |
| User entered empty. | System | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 06 Oct 2020 20:12:38 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 06 Oct 2020 20:12:38 |
| User entered '79' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 06 Oct 2020 20:12:38 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | 06 Oct 2020 19:47:52 |
| User entered empty. | System | 06 Oct 2020 19:47:52 |
| | Cindy Lubbers (b) (4) | 06 Oct 2020 19:47:52 |
| | (b) (4) | |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:56

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered 'mmHg' | System | 06 Oct 2020 20:12:38 |
| User entered empty. | System | 06 Oct 2020 19:47:52 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:56

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 06 Oct 2020 19:48:13 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:56

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '6 Oct 2020' | Cindy Lubbers (b) (4) | 06 Oct 2020 19:48:13 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:56

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 06 Oct 2020 19:49:15 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:56

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered empty. | Cindy Lubbers (b) (4) | 06 Oct 2020 19:49:15 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:56

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) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered empty. | Cindy Lubbers (b) (4) | 06 Oct 2020 19:49:15 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:56

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:56

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '6 Oct 2020' | Cindy Lubbers (b) (4) | 06 Oct 2020 19:49:15 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:56

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '15:27' | Cindy Lubbers (b) (4) | 06 Oct 2020 19:49:15 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:56

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered '6 Oct 2020 15:27' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:56

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Left Arm (LEFT ARM)' | Cindy Lubbers (b) (4) | 06 Oct 2020 19:49:15 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:56

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered 'ONCE' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:56

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered 'INTRAMUSCULAR' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:56

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 06 Oct 2020 19:49:35 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:56

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '6 Oct 2020' | Cindy Lubbers (b) (4) | 06 Oct 2020 19:49:35 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:56

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '15:00' | Cindy Lubbers (b) (4) | 06 Oct 2020 19:49:35 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:56

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered '6 Oct 2020 15:00' | System | 06 Oct 2020 19:49:35 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:09:56

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System). | (b) (4) | |
| Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System). | System | 06 Oct 2020 19:50:45 |
| System | System | 06 Oct 2020 19:50:45 |
| User entered '6 Oct 2020' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 06 Oct 2020 19:50:45 |
| User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System). | (b) (4) | |
| User entered empty. | System | 06 Oct 2020 19:50:35 |
| | Cindy Lubbers (b) (4) | 06 Oct 2020 19:50:35 |
| | (b) (4) | |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:09:56

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Cindy Lubbers (b) (4) (b) (4) | 06 Oct 2020 19:50:35 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:09:56

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Yes (Y)' | (b) (4) Cindy Lubbers (b) (4) | 06 Oct 2020 19:50:35 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:09:56

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '14:45' | Cindy Lubbers (b) (4) | 06 Oct 2020 19:50:35 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:09:56

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered '6 Oct 2020 14:45' | System | 06 Oct 2020 19:50:45 |
| User entered empty. | System | 06 Oct 2020 19:50:35 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:09:56

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Cindy Lubbers (b) (4) (b) (4) | 06 Oct 2020 19:50:35 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:09:56

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 06 Oct 2020 19:50:35 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:09:56

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered empty. | Cindy Lubbers (b) (4) | 06 Oct 2020 19:50:35 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:09:56

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered empty. | System | 06 Oct 2020 19:50:35 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 06 Oct 2020 19:50:53 |

US3532281

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered 'I' | System | 06 Oct 2020 19:50:53 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 06 Oct 2020 19:49:15 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T16:02:36', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '3eabfaad-e2db-4215-b797-406148e18824' User entered 'Yes (Y)' | System | 06 Oct 2020 20:03:01 |
| | System | 06 Oct 2020 20:03:01 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T16:02:46', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '3eabfaad-e2db-4215-b797-406148e18824' User entered '98.5' | System | 06 Oct 2020 20:03:01 |
| | System | 06 Oct 2020 20:03:01 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T16:02:52', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '3eabfaad-e2db-4215-b797-406148e18824' User entered 'No (N)' | System | 06 Oct 2020 20:03:01 |
| | System | 06 Oct 2020 20:03:01 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T16:02:58', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '3eabfaad-e2db-4215-b797-406148e18824' User entered '06 Oct 2020 16:02' | System | 06 Oct 2020 20:03:01 |
| | System | 06 Oct 2020 20:03:01 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '06 Oct 2020 15:47' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '06 Oct 2020 18:17' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 06 Oct 2020 19:49:15 |
| User entered 'Day 1, after vaccination (at home)' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T21:41:15', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '71ea9d28-c6df-4c88-8180-ed21bafc9377' User entered 'Yes (Y)' | System | 07 Oct 2020 01:41:48 |
| | System | 07 Oct 2020 01:41:48 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T21:41:27', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '71ea9d28-c6df-4c88-8180-ed21bafc9377' User entered '97.5' | System | 07 Oct 2020 01:41:48 |
| | System | 07 Oct 2020 01:41:48 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T21:41:32', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '71ea9d28-c6df-4c88-8180-ed21bafc9377' | System | 07 Oct 2020 01:41:48 |
| User entered 'No (N)' | System | 07 Oct 2020 01:41:48 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T21:41:44', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '71ea9d28-c6df-4c88-8180-ed21bafc9377' User entered '06 Oct 2020 21:41' | System | 07 Oct 2020 01:41:48 |
| | System | 07 Oct 2020 01:41:48 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '06 Oct 2020 19:12' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '07 Oct 2020 11:59' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 06 Oct 2020 19:49:15 |
| User entered 'Day 2' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:56

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-07T15:31:06', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'f98caf22-bbbf-48a8-9c52-9c0fe48b8adb' User entered 'Yes (Y)' | System | 07 Oct 2020 19:32:00 |
| | System | 07 Oct 2020 19:32:00 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:56

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-07T15:31:23', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'f98caf22-bbbf-48a8-9c52-9c0fe48b8adb' User entered '99.7' | System | 07 Oct 2020 19:32:00 |
| | System | 07 Oct 2020 19:32:00 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-07T15:31:33', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'f98caf22-bbbf-48a8-9c52-9c0fe48b8adb' User entered 'Yes (Y)' | System | 07 Oct 2020 19:32:00 |
| | System | 07 Oct 2020 19:32:00 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'pain' (Site from System). | (b) (4), (b) (6) | 29 Oct 2020 02:58:35 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-07T15:31:49', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'f98caf22-bbbf-48a8-9c52-9c0fe48b8adb' User entered '1' | Cindy Lubbers (b) (4) | 28 Oct 2020 15:34:46 |
| | System | 07 Oct 2020 19:32:00 |
| | System | 07 Oct 2020 19:32:00 |
| | System | 07 Oct 2020 19:32:00 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:56

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-07T15:31:49', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'f98caf22-bbbf-48a8-9c52-9c0fe48b8adb' User entered '0' | System | 07 Oct 2020 19:32:00 |
| | System | 07 Oct 2020 19:32:00 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-07T15:31:55', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'f98caf22-bbbf-48a8-9c52-9c0fe48b8adb' User entered '07 Oct 2020 15:31' | System | 07 Oct 2020 19:32:00 |
| | System | 07 Oct 2020 19:32:00 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '07 Oct 2020 12:00' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '08 Oct 2020 11:59' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 06 Oct 2020 19:49:15 |
| User entered 'Day 3' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:56

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T02:46:15', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'f3fd252c-73b7-4dd7-81c5-6e603f98fb8b' User entered 'Yes (Y)' | System | 09 Oct 2020 06:46:47 |
| | System | 09 Oct 2020 06:46:47 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:56

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T02:46:30', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'f3fd252c-73b7-4dd7-81c5-6e603f98fb8b' User entered '97.8' | System | 09 Oct 2020 06:46:47 |
| | System | 09 Oct 2020 06:46:47 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T02:46:36', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'f3fd252c-73b7-4dd7-81c5-6e603f98fb8b' | System | 09 Oct 2020 06:46:47 |
| User entered 'No (N)' | System | 09 Oct 2020 06:46:47 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T02:46:43', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'f3fd252c-73b7-4dd7-81c5-6e603f98fb8b' User entered '09 Oct 2020 02:46' | System | 09 Oct 2020 06:46:47 |
| | System | 09 Oct 2020 06:46:47 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '08 Oct 2020 12:00' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '09 Oct 2020 11:59' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 06 Oct 2020 19:49:15 |
| User entered 'Day 4' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:56

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T18:14:12', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '53b35942-b0b4-426b-9889-a37a00e1249f' User entered 'Yes (Y)' | System | 09 Oct 2020 22:14:32 |
| | System | 09 Oct 2020 22:14:32 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:56

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T18:14:19', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '53b35942-b0b4-426b-9889-a37a00e1249f' User entered '98.2' | System | 09 Oct 2020 22:14:32 |
| | System | 09 Oct 2020 22:14:32 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T18:14:24', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '53b35942-b0b4-426b-9889-a37a00e1249f' User entered 'No (N)' | System | 09 Oct 2020 22:14:32 |
| | System | 09 Oct 2020 22:14:32 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T18:14:30', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '53b35942-b0b4-426b-9889-a37a00e1249f' User entered '09 Oct 2020 18:14' | System | 09 Oct 2020 22:14:32 |
| | System | 09 Oct 2020 22:14:32 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '09 Oct 2020 12:00' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '10 Oct 2020 11:59' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 06 Oct 2020 19:49:15 |
| User entered 'Day 5' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:56

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T02:06:57', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'c6ef3ed0-ce7c-4a28-98a6-e6deb091d440' User entered 'Yes (Y)' | System | 11 Oct 2020 06:07:20 |
| | System | 11 Oct 2020 06:07:20 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:56

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T02:07:07', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'c6ef3ed0-ce7c-4a28-98a6-e6deb091d440' User entered '98.6' | System | 11 Oct 2020 06:07:20 |
| | System | 11 Oct 2020 06:07:20 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T02:07:12', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'c6ef3ed0-ce7c-4a28-98a6-e6deb091d440' | System | 11 Oct 2020 06:07:20 |
| User entered 'No (N)' | System | 11 Oct 2020 06:07:20 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T02:07:18', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'c6ef3ed0-ce7c-4a28-98a6-e6deb091d440' User entered '11 Oct 2020 02:07' | System | 11 Oct 2020 06:07:20 |
| | System | 11 Oct 2020 06:07:20 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '10 Oct 2020 12:00' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '11 Oct 2020 11:59' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 06 Oct 2020 19:49:15 |
| User entered 'Day 6' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:56

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T22:22:40', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '5c0028d1-c03f-45ed-9e31-786ac5681407' User entered 'Yes (Y)' | System | 12 Oct 2020 02:23:00 |
| | System | 12 Oct 2020 02:23:00 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:56

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T22:22:45', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '5c0028d1-c03f-45ed-9e31-786ac5681407' User entered '98.7' | System | 12 Oct 2020 02:23:00 |
| | System | 12 Oct 2020 02:23:00 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T22:22:49', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '5c0028d1-c03f-45ed-9e31-786ac5681407' | System | 12 Oct 2020 02:23:00 |
| User entered 'No (N)' | System | 12 Oct 2020 02:23:00 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T22:22:56', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '5c0028d1-c03f-45ed-9e31-786ac5681407' User entered '11 Oct 2020 22:22' | System | 12 Oct 2020 02:23:00 |
| | System | 12 Oct 2020 02:23:00 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '11 Oct 2020 12:00' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '12 Oct 2020 11:59' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 06 Oct 2020 19:49:15 |
| User entered 'Day 7' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:56

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-12T23:20:48', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'a922c224-8b39-469b-b644-c8805eb1ad7f' User entered 'Yes (Y)' | System | 13 Oct 2020 03:21:04 |
| | System | 13 Oct 2020 03:21:04 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:56

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-12T23:20:54', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'a922c224-8b39-469b-b644-c8805eb1ad7f' User entered '98.1' | System | 13 Oct 2020 03:21:04 |
| | System | 13 Oct 2020 03:21:04 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-12T23:20:57', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'a922c224-8b39-469b-b644-c8805eb1ad7f' User entered 'No (N)' | System | 13 Oct 2020 03:21:04 |
| | System | 13 Oct 2020 03:21:04 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-12T23:21:02', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'a922c224-8b39-469b-b644-c8805eb1ad7f' User entered '12 Oct 2020 23:21' | System | 13 Oct 2020 03:21:04 |
| | System | 13 Oct 2020 03:21:04 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '12 Oct 2020 12:00' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '13 Oct 2020 11:59' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 06 Oct 2020 19:49:15 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T16:03:29', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'afa47ba4-1c60-49a2-858b-dffcdb526b2d' | System | 06 Oct 2020 20:03:45 |
| User entered 'None (1)' | System | 06 Oct 2020 20:03:45 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T16:03:32', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'afa47ba4-1c60-49a2-858b-dffcdb526b2d' User entered 'No (N)' | System | 06 Oct 2020 20:03:45 |
| | System | 06 Oct 2020 20:03:45 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T16:03:34', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'afa47ba4-1c60-49a2-858b-dffcdb526b2d' User entered 'No (N)' | System | 06 Oct 2020 20:03:45 |
| | System | 06 Oct 2020 20:03:45 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T16:03:40', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'afa47ba4-1c60-49a2-858b-dffcdb526b2d' User entered 'None (1)' | System | 06 Oct 2020 20:03:45 |
| | System | 06 Oct 2020 20:03:45 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T16:03:43', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'afa47ba4-1c60-49a2-858b-dffcdb526b2d' User entered '06 Oct 2020 16:03' | System | 06 Oct 2020 20:03:45 |
| | System | 06 Oct 2020 20:03:45 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '06 Oct 2020 15:47' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '06 Oct 2020 18:17' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 06 Oct 2020 19:49:15 |
| User entered 'Day 1, after vaccination (at home)' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T21:41:53', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '16915624-17e9-4021-ab3e-7aff25b57f09' | System | 07 Oct 2020 01:42:14 |
| User entered 'None (1)' | System | 07 Oct 2020 01:42:14 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T21:41:58', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '16915624-17e9-4021-ab3e-7aff25b57f09' | System | 07 Oct 2020 01:42:14 |
| User entered 'No (N)' | System | 07 Oct 2020 01:42:14 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T21:42:01', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '16915624-17e9-4021-ab3e-7aff25b57f09' User entered 'No (N)' | System | 07 Oct 2020 01:42:14 |
| | System | 07 Oct 2020 01:42:14 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T21:42:07', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '16915624-17e9-4021-ab3e-7aff25b57f09' | System | 07 Oct 2020 01:42:14 |
| User entered 'None (1)' | System | 07 Oct 2020 01:42:14 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T21:42:12', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '16915624-17e9-4021-ab3e-7aff25b57f09' | System | 07 Oct 2020 01:42:14 |
| User entered '06 Oct 2020 21:42' | System | 07 Oct 2020 01:42:14 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '06 Oct 2020 19:12' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '07 Oct 2020 11:59' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 06 Oct 2020 19:49:15 |
| User entered 'Day 2' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-07T15:32:09', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'b52fc565-561b-41c4-ab34-6f775abf643e' User entered 'None (1)' | System | 07 Oct 2020 19:32:42 |
| | System | 07 Oct 2020 19:32:42 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:56

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-07T15:32:13', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'b52fc565-561b-41c4-ab34-6f775abf643e' User entered 'No (N)' | System | 07 Oct 2020 19:32:42 |
| | System | 07 Oct 2020 19:32:42 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-07T15:32:16', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'b52fc565-561b-41c4-ab34-6f775abf643e' User entered 'No (N)' | System | 07 Oct 2020 19:32:42 |
| | System | 07 Oct 2020 19:32:42 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-07T15:32:28', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'b52fc565-561b-41c4-ab34-6f775abf643e' User entered 'None (1)' | System | 07 Oct 2020 19:32:42 |
| | System | 07 Oct 2020 19:32:42 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-07T15:32:40', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'b52fc565-561b-41c4-ab34-6f775abf643e' User entered '07 Oct 2020 15:32' | System | 07 Oct 2020 19:32:42 |
| | System | 07 Oct 2020 19:32:42 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '07 Oct 2020 12:00' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '08 Oct 2020 11:59' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 06 Oct 2020 19:49:15 |
| User entered 'Day 3' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T02:46:50', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '0d51a3da-21b9-4602-a0f0-17040293921c' User entered 'None (1)' | System | 09 Oct 2020 06:47:12 |
| | System | 09 Oct 2020 06:47:12 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:56

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T02:46:55', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '0d51a3da-21b9-4602-a0f0-17040293921c' User entered 'No (N)' | System | 09 Oct 2020 06:47:12 |
| | System | 09 Oct 2020 06:47:12 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T02:46:59', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '0d51a3da-21b9-4602-a0f0-17040293921c' User entered 'No (N)' | System | 09 Oct 2020 06:47:12 |
| | System | 09 Oct 2020 06:47:12 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T02:47:03', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '0d51a3da-21b9-4602-a0f0-17040293921c' User entered 'None (1)' | System | 09 Oct 2020 06:47:12 |
| | System | 09 Oct 2020 06:47:12 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T02:47:08', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '0d51a3da-21b9-4602-a0f0-17040293921c' User entered '09 Oct 2020 02:47' | System | 09 Oct 2020 06:47:12 |
| | System | 09 Oct 2020 06:47:12 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '08 Oct 2020 12:00' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '09 Oct 2020 11:59' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 06 Oct 2020 19:49:15 |
| User entered 'Day 4' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T18:14:37', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'b35ba8aa-81d3-49bc-bba1-4d3263af8290' | System | 09 Oct 2020 22:15:05 |
| User entered 'None (1)' | System | 09 Oct 2020 22:15:05 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:56

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T18:14:40', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'b35ba8aa-81d3-49bc-bba1-4d3263af8290' User entered 'No (N)' | System | 09 Oct 2020 22:15:05 |
| | System | 09 Oct 2020 22:15:05 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T18:14:49', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'b35ba8aa-81d3-49bc-bba1-4d3263af8290' User entered 'No (N)' | System | 09 Oct 2020 22:15:05 |
| | System | 09 Oct 2020 22:15:05 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T18:14:55', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'b35ba8aa-81d3-49bc-bba1-4d3263af8290' User entered 'None (1)' | System | 09 Oct 2020 22:15:05 |
| | System | 09 Oct 2020 22:15:05 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T18:15:02', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'b35ba8aa-81d3-49bc-bba1-4d3263af8290' User entered '09 Oct 2020 18:15' | System | 09 Oct 2020 22:15:05 |
| | System | 09 Oct 2020 22:15:05 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '09 Oct 2020 12:00' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '10 Oct 2020 11:59' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 06 Oct 2020 19:49:15 |
| User entered 'Day 5' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T02:07:29', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'ea2d7d04-b469-4ebd-9a24-4f0e9a19ae98' | System | 11 Oct 2020 06:08:00 |
| User entered 'None (1)' | System | 11 Oct 2020 06:08:00 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:56

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T02:07:35', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'ea2d7d04-b469-4ebd-9a24-4f0e9a19ae98' | System | 11 Oct 2020 06:08:00 |
| User entered 'No (N)' | System | 11 Oct 2020 06:08:00 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T02:07:39', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'ea2d7d04-b469-4ebd-9a24-4f0e9a19ae98' User entered 'No (N)' | System | 11 Oct 2020 06:08:00 |
| | System | 11 Oct 2020 06:08:00 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T02:07:44', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'ea2d7d04-b469-4ebd-9a24-4f0e9a19ae98' | System | 11 Oct 2020 06:08:00 |
| User entered 'None (1)' | System | 11 Oct 2020 06:08:00 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T02:07:56', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'ea2d7d04-b469-4ebd-9a24-4f0e9a19ae98' User entered '11 Oct 2020 02:07' | System | 11 Oct 2020 06:08:00 |
| | System | 11 Oct 2020 06:08:00 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '10 Oct 2020 12:00' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '11 Oct 2020 11:59' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 06 Oct 2020 19:49:15 |
| User entered 'Day 6' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T22:23:02', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '1baa25af-2d65-4e3e-8e01-1060fa7ff8c5' | System | 12 Oct 2020 02:23:21 |
| User entered 'None (1)' | System | 12 Oct 2020 02:23:21 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:56

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T22:23:06', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '1baa25af-2d65-4e3e-8e01-1060fa7ff8c5' User entered 'No (N)' | System | 12 Oct 2020 02:23:21 |
| | System | 12 Oct 2020 02:23:21 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T22:23:09', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '1baa25af-2d65-4e3e-8e01-1060fa7ff8c5' User entered 'No (N)' | System | 12 Oct 2020 02:23:21 |
| | System | 12 Oct 2020 02:23:21 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T22:23:12', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '1baa25af-2d65-4e3e-8e01-1060fa7ff8c5' | System | 12 Oct 2020 02:23:21 |
| User entered 'None (1)' | System | 12 Oct 2020 02:23:21 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T22:23:18', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '1baa25af-2d65-4e3e-8e01-1060fa7ff8c5' User entered '11 Oct 2020 22:23' | System | 12 Oct 2020 02:23:21 |
| | System | 12 Oct 2020 02:23:21 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '11 Oct 2020 12:00' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '12 Oct 2020 11:59' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 06 Oct 2020 19:49:15 |
| User entered 'Day 7' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-12T23:21:06', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'd0ddb670-3eee-46fc-a775-bb2a05d9931f' User entered 'None (1)' | System | 13 Oct 2020 03:21:23 |
| | System | 13 Oct 2020 03:21:23 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:56

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-12T23:21:10', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'd0ddb670-3eee-46fc-a775-bb2a05d9931f' User entered 'No (N)' | System | 13 Oct 2020 03:21:23 |
| | System | 13 Oct 2020 03:21:23 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-12T23:21:13', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'd0ddb670-3eee-46fc-a775-bb2a05d9931f' User entered 'No (N)' | System | 13 Oct 2020 03:21:23 |
| | System | 13 Oct 2020 03:21:23 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-12T23:21:15', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'd0ddb670-3eee-46fc-a775-bb2a05d9931f' User entered 'None (1)' | System | 13 Oct 2020 03:21:23 |
| | System | 13 Oct 2020 03:21:23 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:56

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-12T23:21:19', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'd0ddb670-3eee-46fc-a775-bb2a05d9931f' User entered '12 Oct 2020 23:21' | System | 13 Oct 2020 03:21:23 |
| | System | 13 Oct 2020 03:21:23 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '12 Oct 2020 12:00' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '13 Oct 2020 11:59' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 06 Oct 2020 19:49:15 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T16:03:55', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'ffcd3b08-b3b7-414e-82dc-c9d517034ce3' User entered 'None (0)' | System | 06 Oct 2020 20:04:20 |
| | System | 06 Oct 2020 20:04:20 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T16:03:58', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'ffcd3b08-b3b7-414e-82dc-c9d517034ce3' User entered 'None (0)' | System | 06 Oct 2020 20:04:20 |
| | System | 06 Oct 2020 20:04:20 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T16:04:01', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'ffcd3b08-b3b7-414e-82dc-c9d517034ce3' User entered 'None (0)' | System | 06 Oct 2020 20:04:20 |
| | System | 06 Oct 2020 20:04:20 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T16:04:03', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'ffcd3b08-b3b7-414e-82dc-c9d517034ce3' User entered 'None (0)' | System | 06 Oct 2020 20:04:20 |
| | System | 06 Oct 2020 20:04:20 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T16:04:05', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'ffcd3b08-b3b7-414e-82dc-c9d517034ce3' User entered 'None (0)' | System | 06 Oct 2020 20:04:20 |
| | System | 06 Oct 2020 20:04:20 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T16:04:07', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'ffcd3b08-b3b7-414e-82dc-c9d517034ce3' User entered 'None (0)' | System | 06 Oct 2020 20:04:20 |
| | System | 06 Oct 2020 20:04:20 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T16:04:16', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'ffcd3b08-b3b7-414e-82dc-c9d517034ce3' User entered 'No (N)' | System | 06 Oct 2020 20:04:20 |
| | System | 06 Oct 2020 20:04:20 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T16:04:19', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'ffcd3b08-b3b7-414e-82dc-c9d517034ce3' User entered '06 Oct 2020 16:04' | System | 06 Oct 2020 20:04:20 |
| | System | 06 Oct 2020 20:04:20 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '06 Oct 2020 15:47' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '06 Oct 2020 18:17' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 06 Oct 2020 19:49:15 |
| User entered 'Day 1, after vaccination (at home)' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T21:42:18', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '2b867b29-a0d1-46ea-b685-de4f40c9707a' User entered 'None (0)' | System | 07 Oct 2020 01:42:48 |
| | System | 07 Oct 2020 01:42:48 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T21:42:20', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '2b867b29-a0d1-46ea-b685-de4f40c9707a' User entered 'None (0)' | System | 07 Oct 2020 01:42:48 |
| | System | 07 Oct 2020 01:42:48 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T21:42:22', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '2b867b29-a0d1-46ea-b685-de4f40c9707a' User entered 'None (0)' | System | 07 Oct 2020 01:42:48 |
| | System | 07 Oct 2020 01:42:48 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T21:42:24', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '2b867b29-a0d1-46ea-b685-de4f40c9707a' User entered 'None (0)' | System | 07 Oct 2020 01:42:48 |
| | System | 07 Oct 2020 01:42:48 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T21:42:27', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '2b867b29-a0d1-46ea-b685-de4f40c9707a' User entered 'None (0)' | System | 07 Oct 2020 01:42:48 |
| | System | 07 Oct 2020 01:42:48 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T21:42:32', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '2b867b29-a0d1-46ea-b685-de4f40c9707a' User entered 'None (0)' | System | 07 Oct 2020 01:42:48 |
| | System | 07 Oct 2020 01:42:48 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T21:42:40', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '2b867b29-a0d1-46ea-b685-de4f40c9707a' User entered 'No (N)' | System | 07 Oct 2020 01:42:48 |
| | System | 07 Oct 2020 01:42:48 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-06T21:42:45', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '2b867b29-a0d1-46ea-b685-de4f40c9707a' User entered '06 Oct 2020 21:42' | System | 07 Oct 2020 01:42:48 |
| | System | 07 Oct 2020 01:42:48 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '06 Oct 2020 19:12' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '07 Oct 2020 11:59' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 06 Oct 2020 19:49:15 |
| User entered 'Day 2' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-07T15:33:57', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '9f0a4fce-8221-4333-9ca7-fc7c51a1ff7a' | System | 07 Oct 2020 19:35:24 |
| User entered 'No interference with activity (1)' | System | 07 Oct 2020 19:35:24 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-07T15:34:03', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '9f0a4fce-8221-4333-9ca7-fc7c51a1ff7a' | System | 07 Oct 2020 19:35:24 |
| User entered 'No interference with activity (1)' | System | 07 Oct 2020 19:35:24 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-07T15:34:25', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '9f0a4fce-8221-4333-9ca7-fc7c51a1ff7a' | System | 07 Oct 2020 19:35:24 |
| User entered 'No interference with activity (1)' | System | 07 Oct 2020 19:35:24 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-07T15:34:30', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '9f0a4fce-8221-4333-9ca7-fc7c51a1ff7a' | System | 07 Oct 2020 19:35:24 |
| User entered 'No interference with activity (1)' | System | 07 Oct 2020 19:35:24 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-07T15:34:33', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '9f0a4fce-8221-4333-9ca7-fc7c51a1ff7a' User entered 'None (0)' | System | 07 Oct 2020 19:35:24 |
| | System | 07 Oct 2020 19:35:24 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-07T15:34:42', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '9f0a4fce-8221-4333-9ca7-fc7c51a1ff7a' | System | 07 Oct 2020 19:35:24 |
| User entered 'Some interference with activity not requiring medical attention (2)' | System | 07 Oct 2020 19:35:24 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-07T15:35:16', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '9f0a4fce-8221-4333-9ca7-fc7c51a1ff7a' | System | 07 Oct 2020 19:35:24 |
| User entered 'No (N)' | System | 07 Oct 2020 19:35:24 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-07T15:35:20', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '9f0a4fce-8221-4333-9ca7-fc7c51a1ff7a' User entered '07 Oct 2020 15:35' | System | 07 Oct 2020 19:35:24 |
| | System | 07 Oct 2020 19:35:24 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '07 Oct 2020 12:00' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '08 Oct 2020 11:59' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 06 Oct 2020 19:49:15 |
| User entered 'Day 3' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T02:47:14', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '2431d774-eba3-413b-a9ec-b7bf40ec0d5e' User entered 'None (0)' | System | 09 Oct 2020 06:47:44 |
| | System | 09 Oct 2020 06:47:44 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T02:47:19', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '2431d774-eba3-413b-a9ec-b7bf40ec0d5e' | System | 09 Oct 2020 06:47:44 |
| User entered 'No interference with activity (1)' | System | 09 Oct 2020 06:47:44 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T02:47:24', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '2431d774-eba3-413b-a9ec-b7bf40ec0d5e' User entered 'None (0)' | System | 09 Oct 2020 06:47:44 |
| | System | 09 Oct 2020 06:47:44 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T02:47:26', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '2431d774-eba3-413b-a9ec-b7bf40ec0d5e' User entered 'None (0)' | System | 09 Oct 2020 06:47:44 |
| | System | 09 Oct 2020 06:47:44 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T02:47:29', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '2431d774-eba3-413b-a9ec-b7bf40ec0d5e' User entered 'None (0)' | System | 09 Oct 2020 06:47:44 |
| | System | 09 Oct 2020 06:47:44 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T02:47:31', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '2431d774-eba3-413b-a9ec-b7bf40ec0d5e' User entered 'None (0)' | System | 09 Oct 2020 06:47:44 |
| | System | 09 Oct 2020 06:47:44 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T02:47:37', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '2431d774-eba3-413b-a9ec-b7bf40ec0d5e' User entered 'No (N)' | System | 09 Oct 2020 06:47:44 |
| | System | 09 Oct 2020 06:47:44 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T02:47:40', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '2431d774-eba3-413b-a9ec-b7bf40ec0d5e' User entered '09 Oct 2020 02:47' | System | 09 Oct 2020 06:47:44 |
| | System | 09 Oct 2020 06:47:44 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '08 Oct 2020 12:00' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '09 Oct 2020 11:59' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 06 Oct 2020 19:49:15 |
| User entered 'Day 4' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T18:15:16', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '53be2ae1-f0df-4d74-b26d-6f1b4b8f019f' User entered 'None (0)' | System | 09 Oct 2020 22:15:50 |
| | System | 09 Oct 2020 22:15:50 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T18:15:24', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '53be2ae1-f0df-4d74-b26d-6f1b4b8f019f' User entered 'None (0)' | System | 09 Oct 2020 22:15:50 |
| | System | 09 Oct 2020 22:15:50 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T18:15:27', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '53be2ae1-f0df-4d74-b26d-6f1b4b8f019f' User entered 'None (0)' | System | 09 Oct 2020 22:15:50 |
| | System | 09 Oct 2020 22:15:50 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T18:15:30', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '53be2ae1-f0df-4d74-b26d-6f1b4b8f019f' User entered 'None (0)' | System | 09 Oct 2020 22:15:50 |
| | System | 09 Oct 2020 22:15:50 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T18:15:33', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '53be2ae1-f0df-4d74-b26d-6f1b4b8f019f' User entered 'None (0)' | System | 09 Oct 2020 22:15:50 |
| | System | 09 Oct 2020 22:15:50 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T18:15:36', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '53be2ae1-f0df-4d74-b26d-6f1b4b8f019f' User entered 'None (0)' | System | 09 Oct 2020 22:15:50 |
| | System | 09 Oct 2020 22:15:50 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T18:15:45', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '53be2ae1-f0df-4d74-b26d-6f1b4b8f019f' User entered 'No (N)' | System | 09 Oct 2020 22:15:50 |
| | System | 09 Oct 2020 22:15:50 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-09T18:15:47', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '53be2ae1-f0df-4d74-b26d-6f1b4b8f019f' User entered '09 Oct 2020 18:15' | System | 09 Oct 2020 22:15:50 |
| | System | 09 Oct 2020 22:15:50 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '09 Oct 2020 12:00' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '10 Oct 2020 11:59' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 06 Oct 2020 19:49:15 |
| User entered 'Day 5' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T02:08:03', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '5c232456-07a6-4f0d-948f-db7ee94babb1' User entered 'None (0)' | System | 11 Oct 2020 06:09:01 |
| | System | 11 Oct 2020 06:09:01 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T02:08:07', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '5c232456-07a6-4f0d-948f-db7ee94babb1' User entered 'None (0)' | System | 11 Oct 2020 06:09:01 |
| | System | 11 Oct 2020 06:09:01 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T02:08:10', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '5c232456-07a6-4f0d-948f-db7ee94babb1' User entered 'None (0)' | System | 11 Oct 2020 06:09:01 |
| | System | 11 Oct 2020 06:09:01 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T02:08:15', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '5c232456-07a6-4f0d-948f-db7ee94babb1' User entered 'None (0)' | System | 11 Oct 2020 06:09:01 |
| | System | 11 Oct 2020 06:09:01 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T02:08:18', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '5c232456-07a6-4f0d-948f-db7ee94babb1' User entered 'None (0)' | System | 11 Oct 2020 06:09:01 |
| | System | 11 Oct 2020 06:09:01 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T02:08:21', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '5c232456-07a6-4f0d-948f-db7ee94babb1' User entered 'None (0)' | System | 11 Oct 2020 06:09:01 |
| | System | 11 Oct 2020 06:09:01 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T02:08:42', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '5c232456-07a6-4f0d-948f-db7ee94babb1' User entered 'No (N)' | System | 11 Oct 2020 06:09:01 |
| | System | 11 Oct 2020 06:09:01 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T02:08:59', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '5c232456-07a6-4f0d-948f-db7ee94babb1' User entered '11 Oct 2020 02:08' | System | 11 Oct 2020 06:09:01 |
| | System | 11 Oct 2020 06:09:01 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '10 Oct 2020 12:00' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '11 Oct 2020 11:59' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 06 Oct 2020 19:49:15 |
| User entered 'Day 6' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T22:23:24', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'a6f84ae4-66b6-472c-9a4d-d6b9e30d6b7c' User entered 'None (0)' | System | 12 Oct 2020 02:23:56 |
| | System | 12 Oct 2020 02:23:56 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T22:23:27', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'a6f84ae4-66b6-472c-9a4d-d6b9e30d6b7c' User entered 'None (0)' | System | 12 Oct 2020 02:23:56 |
| | System | 12 Oct 2020 02:23:56 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T22:23:29', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'a6f84ae4-66b6-472c-9a4d-d6b9e30d6b7c' User entered 'None (0)' | System | 12 Oct 2020 02:23:56 |
| | System | 12 Oct 2020 02:23:56 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T22:23:33', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'a6f84ae4-66b6-472c-9a4d-d6b9e30d6b7c' User entered 'None (0)' | System | 12 Oct 2020 02:23:56 |
| | System | 12 Oct 2020 02:23:56 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T22:23:36', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'a6f84ae4-66b6-472c-9a4d-d6b9e30d6b7c' User entered 'None (0)' | System | 12 Oct 2020 02:23:56 |
| | System | 12 Oct 2020 02:23:56 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T22:23:39', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'a6f84ae4-66b6-472c-9a4d-d6b9e30d6b7c' User entered 'None (0)' | System | 12 Oct 2020 02:23:56 |
| | System | 12 Oct 2020 02:23:56 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T22:23:48', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'a6f84ae4-66b6-472c-9a4d-d6b9e30d6b7c' User entered 'No (N)' | System | 12 Oct 2020 02:23:56 |
| | System | 12 Oct 2020 02:23:56 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-11T22:23:54', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'a6f84ae4-66b6-472c-9a4d-d6b9e30d6b7c' User entered '11 Oct 2020 22:23' | System | 12 Oct 2020 02:23:56 |
| | System | 12 Oct 2020 02:23:56 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '11 Oct 2020 12:00' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '12 Oct 2020 11:59' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 06 Oct 2020 19:49:15 |
| User entered 'Day 7' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-12T23:21:25', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '444c6c73-a531-4991-97c9-ecab2be14374' User entered 'None (0)' | System | 13 Oct 2020 03:21:47 |
| | System | 13 Oct 2020 03:21:47 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-12T23:21:27', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '444c6c73-a531-4991-97c9-ecab2be14374' User entered 'None (0)' | System | 13 Oct 2020 03:21:47 |
| | System | 13 Oct 2020 03:21:47 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-12T23:21:29', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '444c6c73-a531-4991-97c9-ecab2be14374' User entered 'None (0)' | System | 13 Oct 2020 03:21:47 |
| | System | 13 Oct 2020 03:21:47 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-12T23:21:31', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '444c6c73-a531-4991-97c9-ecab2be14374' User entered 'None (0)' | System | 13 Oct 2020 03:21:47 |
| | System | 13 Oct 2020 03:21:47 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-12T23:21:33', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '444c6c73-a531-4991-97c9-ecab2be14374' User entered 'None (0)' | System | 13 Oct 2020 03:21:47 |
| | System | 13 Oct 2020 03:21:47 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-12T23:21:35', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '444c6c73-a531-4991-97c9-ecab2be14374' User entered 'None (0)' | System | 13 Oct 2020 03:21:47 |
| | System | 13 Oct 2020 03:21:47 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-12T23:21:42', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '444c6c73-a531-4991-97c9-ecab2be14374' User entered 'No (N)' | System | 13 Oct 2020 03:21:47 |
| | System | 13 Oct 2020 03:21:47 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-10-12T23:21:45', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '444c6c73-a531-4991-97c9-ecab2be14374' User entered '12 Oct 2020 23:21' | System | 13 Oct 2020 03:21:47 |
| | System | 13 Oct 2020 03:21:47 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '12 Oct 2020 12:00' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:56

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| User entered '13 Oct 2020 11:59' | System | 06 Oct 2020 19:49:15 |

US3532281

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Yes (Y)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 13 Oct 2020 19:05:08 |

US3532281

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered '13 Oct 2020' | Cindy Lubbers (b) (4) | 13 Oct 2020 19:05:08 |

US3532281

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 13 Oct 2020 19:05:08 |

US3532281

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered empty. | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 13 Oct 2020 19:05:08 |

US3532281

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 22 Feb 2021 11:10:12 |
| User entered 'Yes (Y)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 13 Oct 2020 19:05:11 |

US3532281

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered 'I' | System | 13 Oct 2020 19:05:11 |

US3532281

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 20 Oct 2020 19:12:08 |

US3532281

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '20 Oct 2020' | Cindy Lubbers (b) (4) | 20 Oct 2020 19:12:08 |

US3532281

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 20 Oct 2020 19:12:08 |

US3532281

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered empty. | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 20 Oct 2020 19:12:08 |

US3532281

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 20 Oct 2020 19:12:11 |

US3532281

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered 'I' | System | 20 Oct 2020 19:12:11 |

US3532281

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:06:54 |

US3532281

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '27 Oct 2020' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:06:54 |

US3532281

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Contact Made (CONTACT MADE)' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:06:54 |

US3532281

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered empty. | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 27 Oct 2020 17:06:54 |

US3532281

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:06:58 |

US3532281

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered 'I' | System | 27 Oct 2020 17:06:58 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:56

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Yes (Y)' | (b) (4) Cindy Lubbers (b) (4) | 04 Nov 2020 19:55:21 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '04 Nov 2020' reason for change: Data Entry Error | (b) (4) | 12 Nov 2020 15:11:59 |
| User entered '4 Nov 2020' | Kathy Stephens (b) (4) | 12 Nov 2020 15:11:59 |
| | (b) (4) | |
| | Cindy Lubbers (b) (4) | 04 Nov 2020 19:55:21 |
| | (b) (4) | |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Clinic (Clinic)' | Cindy Lubbers (b) (4) | 04 Nov 2020 19:55:21 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:56

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered 'VISIT3' | System | 04 Nov 2020 19:55:21 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 04 Nov 2020 20:02:10 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

Date of assessment (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User closed query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 13 Nov 2020 10:58:01 |
| Query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' answered with 'done' (Site from DM). | Kathy Stephens (b) (4) (b) (4) | 12 Nov 2020 14:53:30 |
| User entered '04 Nov 2020' reason for change: Data Entry Error | Kathy Stephens (b) (4) (b) (4) | 12 Nov 2020 14:53:22 |
| User opened query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' (Site from DM). | (b) (4), (b) (6) | 12 Nov 2020 11:52:40 |
| User entered '4 Nov 2020' | Cindy Lubbers (b) (4) (b) (4) | 04 Nov 2020 20:02:10 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '14:17' | Cindy Lubbers (b) (4) | 04 Nov 2020 20:02:10 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered '04 Nov 2020 14:17' | System | 12 Nov 2020 14:53:22 |
| User entered '4 Nov 2020 14:17' | System | 04 Nov 2020 20:02:10 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '97.5' F | Cindy Lubbers (b) (4) | 04 Nov 2020 20:02:10 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Oral (Oral)' | Cindy Lubbers (b) (4) | 04 Nov 2020 20:02:10 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered empty. | Cindy Lubbers (b) (4) | 04 Nov 2020 20:02:10 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '65' | Cindy Lubbers (b) (4) | 04 Nov 2020 20:02:10 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered 'bpm' | System | 04 Nov 2020 20:02:10 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '18' | Cindy Lubbers (b) (4) | 04 Nov 2020 20:02:10 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered 'breaths/min' | System | 04 Nov 2020 20:02:10 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '147' | Cindy Lubbers (b) (4) | 04 Nov 2020 20:02:10 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered 'mmHg' | System | 04 Nov 2020 20:02:10 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '86' | Cindy Lubbers (b) (4) | 04 Nov 2020 20:02:10 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered 'mmHg' | System | 04 Nov 2020 20:02:10 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| | | |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| | | |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:56

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 04 Nov 2020 20:02:17 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:56

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered empty. | Cindy Lubbers (b) (4) | 04 Nov 2020 20:02:17 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:56

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 04 Nov 2020 20:03:07 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:56

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '04 Nov 2020' reason for change: Data Entry Error | (b) (4) | 12 Nov 2020 15:12:06 |
| User entered '4 Nov 2020' | Kathy Stephens (b) (4) | 12 Nov 2020 15:12:06 |
| | (b) (4) | |
| | Cindy Lubbers (b) (4) | 04 Nov 2020 20:03:07 |
| | (b) (4) | |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:56

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered '14:24' | Cindy Lubbers (b) (4) | 04 Nov 2020 20:03:07 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:56

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered '04 Nov 2020 14:24' | System | 12 Nov 2020 15:12:06 |
| User entered '4 Nov 2020 14:24' | System | 04 Nov 2020 20:03:07 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User signature succeeded. | Evan Anderson (b) (4) | 12 Feb 2021 20:34:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 04 Nov 2020 20:03:12 |

US3532281

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 07 Apr 2021 02:02:40 |
| User entered 'I' | System | 04 Nov 2020 20:03:12 |

US3532281

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 64' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-11-13T17:59:25', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '3ccb01c7-2f9e-4d47-a3d0-ea1e8b64f09d' | System | 13 Nov 2020 22:59:39 |
| User entered 'No (N)' | System | 13 Nov 2020 22:59:39 |

US3532281

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

Have you been exposed to someone with 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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-11-13T17:59:32', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '3ccb01c7-2f9e-4d47-a3d0-ea1e8b64f09d' | System | 13 Nov 2020 22:59:39 |
| User entered 'No (N)' | System | 13 Nov 2020 22:59:39 |

US3532281

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-11-13T17:59:37', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '3ccb01c7-2f9e-4d47-a3d0-ea1e8b64f09d' User entered '13 Nov 2020 17:59:37' | System | 13 Nov 2020 22:59:39 |
| | System | 13 Nov 2020 22:59:39 |

US3532281

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered '10 Nov 2020 00:01' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered '14 Nov 2020 23:59' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered 'Day 71' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-11-17T13:08:42', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '62962d26-f9bc-4e23-b2d9-54692f8c2463' User entered 'No (N)' | System | 17 Nov 2020 18:09:02 |
| | System | 17 Nov 2020 18:09:02 |

US3532281

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

Have you been exposed to someone with 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 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-11-17T13:08:49', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '62962d26-f9bc-4e23-b2d9-54692f8c2463' User entered 'No (N)' | System | 17 Nov 2020 18:09:02 |
| | System | 17 Nov 2020 18:09:02 |

US3532281

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-11-17T13:08:58', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '62962d26-f9bc-4e23-b2d9-54692f8c2463' User entered '17 Nov 2020 13:08:58' | System | 17 Nov 2020 18:09:02 |
| | System | 17 Nov 2020 18:09:02 |

US3532281

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered '17 Nov 2020 00:01' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 05:45:25 |
| Data entry locked. | System | 10 Sep 2020 18:56:35 |
| User entered '21 Nov 2020 23:59' | System | 10 Sep 2020 18:56:35 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 75' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-11-21T09:49:46', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '66d06883-8f1c-4f3f-9ccc-3cc347cab5a6' | System | 21 Nov 2020 14:50:36 |
| User entered 'No (N)' | System | 21 Nov 2020 14:50:36 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

Have you been exposed to someone with 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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-11-21T09:50:14', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '66d06883-8f1c-4f3f-9ccc-3cc347cab5a6' | System | 21 Nov 2020 14:50:36 |
| User entered 'No (N)' | System | 21 Nov 2020 14:50:36 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-11-21T09:50:31', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '66d06883-8f1c-4f3f-9ccc-3cc347cab5a6' User entered '21 Nov 2020 09:50:31' | System | 21 Nov 2020 14:50:36 |
| | System | 21 Nov 2020 14:50:36 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '21 Nov 2020 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '25 Nov 2020 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 82' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-11-30T15:49:07', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'acc7e7fb-ccb5-4b74-a0a4-0ba176b0ef70' | System | 30 Nov 2020 20:49:37 |
| User entered 'No (N)' | System | 30 Nov 2020 20:49:37 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

Have you been exposed to someone with 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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-11-30T15:49:23', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'acc7e7fb-ccb5-4b74-a0a4-0ba176b0ef70' | System | 30 Nov 2020 20:49:37 |
| User entered 'No (N)' | System | 30 Nov 2020 20:49:37 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-11-30T15:49:31', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'acc7e7fb-ccb5-4b74-a0a4-0ba176b0ef70' User entered '30 Nov 2020 15:49:31' | System | 30 Nov 2020 20:49:37 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '28 Nov 2020 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '02 Dec 2020 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 89' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-12-05T09:21:52', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '89635c37-6e46-49b4-89b6-98b162605d4b' User entered 'No (N)' | System | 05 Dec 2020 14:22:15 |
| | System | 05 Dec 2020 14:22:15 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

Have you been exposed to someone with 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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-12-05T09:22:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '89635c37-6e46-49b4-89b6-98b162605d4b' User entered 'No (N)' | System | 05 Dec 2020 14:22:15 |
| | System | 05 Dec 2020 14:22:15 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-12-05T09:22:10', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '89635c37-6e46-49b4-89b6-98b162605d4b' User entered '05 Dec 2020 09:22:10' | System | 05 Dec 2020 14:22:15 |
| | System | 05 Dec 2020 14:22:15 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '05 Dec 2020 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '09 Dec 2020 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 96' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-12-12T00:57:42', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '8a5b1c99-64e4-44a6-a5ef-dfe78d3ae463' | System | 12 Dec 2020 05:58:07 |
| User entered 'No (N)' | System | 12 Dec 2020 05:58:07 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

Have you been exposed to someone with 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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-12-12T00:57:51', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '8a5b1c99-64e4-44a6-a5ef-dfe78d3ae463' | System | 12 Dec 2020 05:58:07 |
| User entered 'No (N)' | System | 12 Dec 2020 05:58:07 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-12-12T00:58:04', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '8a5b1c99-64e4-44a6-a5ef-dfe78d3ae463' User entered '12 Dec 2020 00:58:04' | System | 12 Dec 2020 05:58:07 |
| | System | 12 Dec 2020 05:58:07 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '12 Dec 2020 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '16 Dec 2020 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 103' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-12-19T10:23:30', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '00da9fc2-09d8-4da9-8e08-431f8f12d2f9' User entered 'No (N)' | System | 19 Dec 2020 15:23:49 |
| | System | 19 Dec 2020 15:23:49 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

Have you been exposed to someone with 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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-12-19T10:23:41', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '00da9fc2-09d8-4da9-8e08-431f8f12d2f9' | System | 19 Dec 2020 15:23:49 |
| User entered 'No (N)' | System | 19 Dec 2020 15:23:49 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-12-19T10:23:46', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '00da9fc2-09d8-4da9-8e08-431f8f12d2f9' User entered '19 Dec 2020 10:23:46' | System | 19 Dec 2020 15:23:49 |
| | System | 19 Dec 2020 15:23:49 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '19 Dec 2020 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '23 Dec 2020 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 110' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-12-26T00:04:35', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '337457b3-14a5-45b5-8c23-37c11f31d768' | System | 26 Dec 2020 05:04:55 |
| User entered 'No (N)' | System | 26 Dec 2020 05:04:55 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

Have you been exposed to someone with 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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-12-26T00:04:45', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '337457b3-14a5-45b5-8c23-37c11f31d768' | System | 26 Dec 2020 05:04:55 |
| User entered 'No (N)' | System | 26 Dec 2020 05:04:55 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2020-12-26T00:04:51', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '337457b3-14a5-45b5-8c23-37c11f31d768' User entered '26 Dec 2020 00:04:51' | System | 26 Dec 2020 05:04:55 |
| | System | 26 Dec 2020 05:04:55 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '26 Dec 2020 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '30 Dec 2020 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 117' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-01-02T11:10:58', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'e4f5e035-9040-40cd-9212-02e37789f2b6' | System | 02 Jan 2021 16:11:11 |
| User entered 'No (N)' | System | 02 Jan 2021 16:11:11 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Have you been exposed to someone with 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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-01-02T11:11:04', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'e4f5e035-9040-40cd-9212-02e37789f2b6' | System | 02 Jan 2021 16:11:11 |
| User entered 'No (N)' | System | 02 Jan 2021 16:11:11 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-01-02T11:11:08', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'e4f5e035-9040-40cd-9212-02e37789f2b6' User entered '02 Jan 2021 11:11:08' | System | 02 Jan 2021 16:11:11 |
| | System | 02 Jan 2021 16:11:11 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '02 Jan 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '06 Jan 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 124' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-01-10T00:58:28', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '69b1c263-028c-4ddc-88a9-343dc3938e16' | System | 10 Jan 2021 05:58:50 |
| User entered 'No (N)' | System | 10 Jan 2021 05:58:50 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

Have you been exposed to someone with 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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-01-10T00:58:42', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '69b1c263-028c-4ddc-88a9-343dc3938e16' | System | 10 Jan 2021 05:58:50 |
| User entered 'No (N)' | System | 10 Jan 2021 05:58:50 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-01-10T00:58:48', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '69b1c263-028c-4ddc-88a9-343dc3938e16' User entered '10 Jan 2021 00:58:48' | System | 10 Jan 2021 05:58:50 |
| | System | 10 Jan 2021 05:58:50 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '09 Jan 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '13 Jan 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 131' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-01-16T04:09:12', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '10db11e5-1cc2-43f9-a080-8b06d1bbef7c' User entered 'No (N)' | System | 16 Jan 2021 09:09:36 |
| | System | 16 Jan 2021 09:09:36 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

Have you been exposed to someone with 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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-01-16T04:09:20', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '10db11e5-1cc2-43f9-a080-8b06d1bbef7c' | System | 16 Jan 2021 09:09:36 |
| User entered 'No (N)' | System | 16 Jan 2021 09:09:36 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-01-16T04:09:31', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '10db11e5-1cc2-43f9-a080-8b06d1bbef7c' User entered '16 Jan 2021 04:09:31' | System | 16 Jan 2021 09:09:36 |
| | System | 16 Jan 2021 09:09:36 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '16 Jan 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '20 Jan 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 138' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-01-23T00:01:52', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '49766533-ac59-4c1a-a571-50a2044390da' User entered 'No (N)' | System | 23 Jan 2021 05:02:43 |
| | System | 23 Jan 2021 05:02:43 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

Have you been exposed to someone with 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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-01-23T00:02:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '49766533-ac59-4c1a-a571-50a2044390da' User entered 'No (N)' | System | 23 Jan 2021 05:02:43 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-01-23T00:02:05', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '49766533-ac59-4c1a-a571-50a2044390da' User entered '23 Jan 2021 00:02:05' | System | 23 Jan 2021 05:02:43 |
| | System | 23 Jan 2021 05:02:43 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '23 Jan 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '27 Jan 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 145' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-01-30T10:24:49', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '94bb3417-fe1f-4451-8a40-919d2bdc081d' User entered 'No (N)' | System | 30 Jan 2021 15:25:06 |
| | System | 30 Jan 2021 15:25:06 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

Have you been exposed to someone with 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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-01-30T10:24:58', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '94bb3417-fe1f-4451-8a40-919d2bdc081d' User entered 'No (N)' | System | 30 Jan 2021 15:25:06 |
| | System | 30 Jan 2021 15:25:06 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-01-30T10:25:02', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '94bb3417-fe1f-4451-8a40-919d2bdc081d' User entered '30 Jan 2021 10:25:02' | System | 30 Jan 2021 15:25:06 |
| | System | 30 Jan 2021 15:25:06 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '30 Jan 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '03 Feb 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 152' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-02-06T09:47:42', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '88d204cd-b14c-4b01-993e-c661f954ade0' User entered 'No (N)' | System | 06 Feb 2021 14:47:57 |
| | System | 06 Feb 2021 14:47:57 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Have you been exposed to someone with 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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-02-06T09:47:50', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '88d204cd-b14c-4b01-993e-c661f954ade0' User entered 'No (N)' | System | 06 Feb 2021 14:47:57 |
| | System | 06 Feb 2021 14:47:57 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-02-06T09:47:54', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '88d204cd-b14c-4b01-993e-c661f954ade0' User entered '06 Feb 2021 09:47:54' | System | 06 Feb 2021 14:47:57 |
| | System | 06 Feb 2021 14:47:57 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '06 Feb 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '10 Feb 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 159' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-02-15T12:17:55', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '85eebe11-49f6-4e02-b27e-e7a4f4e80a0b' User entered 'No (N)' | System | 15 Feb 2021 17:20:30 |
| | System | 15 Feb 2021 17:20:30 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

Have you been exposed to someone with 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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-02-15T12:17:59', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '85eebe11-49f6-4e02-b27e-e7a4f4e80a0b' User entered 'No (N)' | System | 15 Feb 2021 17:20:30 |
| | System | 15 Feb 2021 17:20:30 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-02-15T12:18:03', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '85eebe11-49f6-4e02-b27e-e7a4f4e80a0b' User entered '15 Feb 2021 12:18:03' | System | 15 Feb 2021 17:20:30 |
| | System | 15 Feb 2021 17:20:30 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '13 Feb 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '17 Feb 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 166' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-02-22T12:22:20', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '54b49206-6b8b-4425-9d16-24c729906a75' | System | 22 Feb 2021 17:22:39 |
| User entered 'No (N)' | System | 22 Feb 2021 17:22:39 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

Have you been exposed to someone with 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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-02-22T12:22:24', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '54b49206-6b8b-4425-9d16-24c729906a75' | System | 22 Feb 2021 17:22:39 |
| User entered 'No (N)' | System | 22 Feb 2021 17:22:39 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-02-22T12:22:35', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '54b49206-6b8b-4425-9d16-24c729906a75' | System | 22 Feb 2021 17:22:39 |
| User entered '22 Feb 2021 12:22:35' | System | 22 Feb 2021 17:22:39 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '20 Feb 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '24 Feb 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 173' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-02-27T09:29:24-05:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'fd4b3414-6d02-4e87-98ca-b597e0783c94' | System | 27 Feb 2021 14:29:39 |
| User entered 'No (N)' | System | 27 Feb 2021 14:29:39 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

Have you been exposed to someone with 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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-02-27T09:29:30-05:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'fd4b3414-6d02-4e87-98ca-b597e0783c94' | System | 27 Feb 2021 14:29:39 |
| User entered 'No (N)' | System | 27 Feb 2021 14:29:39 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-02-27T09:29:35-05:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'fd4b3414-6d02-4e87-98ca-b597e0783c94' | System | 27 Feb 2021 14:29:39 |
| User entered '27 Feb 2021 14:29:35' | System | 27 Feb 2021 14:29:39 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '27 Feb 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '03 Mar 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 180' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-03-06T13:58:12-05:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'b1f21cc3-8fe1-4661-9aab-eb9110eaeed7' | System | 06 Mar 2021 18:58:34 |
| User entered 'No (N)' | System | 06 Mar 2021 18:58:34 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

Have you been exposed to someone with 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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-03-06T13:58:26-05:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'b1f21cc3-8fe1-4661-9aab-eb9110eaeed7' | System | 06 Mar 2021 18:58:34 |
| User entered 'No (N)' | System | 06 Mar 2021 18:58:34 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-03-06T13:58:31-05:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'b1f21cc3-8fe1-4661-9aab-eb9110eaeed7' User entered '06 Mar 2021 18:58:31' | System | 06 Mar 2021 18:58:34 |
| | System | 06 Mar 2021 18:58:34 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '06 Mar 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '10 Mar 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 187' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-03-16T16:31:50-04:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '1e3a09df-005a-4cbc-aa29-f8c514a00aa7' | System | 16 Mar 2021 20:32:13 |
| User entered 'No (N)' | System | 16 Mar 2021 20:32:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

Have you been exposed to someone with 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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-03-16T16:32:01-04:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '1e3a09df-005a-4cbc-aa29-f8c514a00aa7' | System | 16 Mar 2021 20:32:13 |
| User entered 'No (N)' | System | 16 Mar 2021 20:32:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-03-16T16:32:04-04:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '1e3a09df-005a-4cbc-aa29-f8c514a00aa7' User entered '16 Mar 2021 16:32:04' | System | 16 Mar 2021 20:32:13 |
| | System | 16 Mar 2021 20:32:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '13 Mar 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '17 Mar 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 194' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-03-23T17:26:27-04:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'df58e985-e42b-4f68-8f68-d55fb029c144' | System | 23 Mar 2021 21:26:40 |
| User entered 'No (N)' | System | 23 Mar 2021 21:26:40 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

Have you been exposed to someone with 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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-03-23T17:26:33-04:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'df58e985-e42b-4f68-8f68-d55fb029c144' | System | 23 Mar 2021 21:26:40 |
| User entered 'No (N)' | System | 23 Mar 2021 21:26:40 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-03-23T17:26:37-04:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'df58e985-e42b-4f68-8f68-d55fb029c144' | System | 23 Mar 2021 21:26:40 |
| User entered '23 Mar 2021 17:26:37' | System | 23 Mar 2021 21:26:40 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '20 Mar 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '24 Mar 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 201' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-03-27T08:49:50-04:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '2a5dd562-be01-42c9-b362-0da1658d1772' | System | 27 Mar 2021 12:50:06 |
| User entered 'No (N)' | System | 27 Mar 2021 12:50:06 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

Have you been exposed to someone with 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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-03-27T08:49:58-04:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '2a5dd562-be01-42c9-b362-0da1658d1772' | System | 27 Mar 2021 12:50:06 |
| User entered 'No (N)' | System | 27 Mar 2021 12:50:06 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-03-27T08:50:00-04:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '2a5dd562-be01-42c9-b362-0da1658d1772' | System | 27 Mar 2021 12:50:06 |
| User entered '27 Mar 2021 08:50:00' | System | 27 Mar 2021 12:50:06 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '27 Mar 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '31 Mar 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 208' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-04-03T09:03:55-04:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '7a14b029-8a13-4aaf-9ba1-fa175d1c0302' | System | 03 Apr 2021 13:04:06 |
| User entered 'No (N)' | System | 03 Apr 2021 13:04:06 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

Have you been exposed to someone with 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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-04-03T09:03:56-04:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '7a14b029-8a13-4aaf-9ba1-fa175d1c0302' | System | 03 Apr 2021 13:04:06 |
| User entered 'No (N)' | System | 03 Apr 2021 13:04:06 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-04-03T09:04:00-04:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '7a14b029-8a13-4aaf-9ba1-fa175d1c0302' | System | 03 Apr 2021 13:04:06 |
| User entered '03 Apr 2021 09:04:00' | System | 03 Apr 2021 13:04:06 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '03 Apr 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '07 Apr 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 215' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-04-10T08:15:05-04:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '33d82ecc-d805-4b1f-8b98-8761ed00f3a4' | System | 10 Apr 2021 12:15:16 |
| User entered 'No (N)' | System | 10 Apr 2021 12:15:16 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

Have you been exposed to someone with 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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-04-10T08:15:09-04:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '33d82ecc-d805-4b1f-8b98-8761ed00f3a4' | System | 10 Apr 2021 12:15:16 |
| User entered 'No (N)' | System | 10 Apr 2021 12:15:16 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-04-10T08:15:14-04:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '33d82ecc-d805-4b1f-8b98-8761ed00f3a4' User entered '10 Apr 2021 08:15:14' | System | 10 Apr 2021 12:15:16 |
| | System | 10 Apr 2021 12:15:16 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '10 Apr 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '14 Apr 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 222' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-04-17T00:20:04-04:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '8570aac5-762d-4301-96b0-7fa308b11be1' | System | 17 Apr 2021 04:20:27 |
| User entered 'No (N)' | System | 17 Apr 2021 04:20:27 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Have you been exposed to someone with 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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-04-17T00:20:14-04:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '8570aac5-762d-4301-96b0-7fa308b11be1' | System | 17 Apr 2021 04:20:27 |
| User entered 'No (N)' | System | 17 Apr 2021 04:20:27 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-04-17T00:20:24-04:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '8570aac5-762d-4301-96b0-7fa308b11be1' | System | 17 Apr 2021 04:20:27 |
| User entered '17 Apr 2021 00:20:24' | System | 17 Apr 2021 04:20:27 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '17 Apr 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '21 Apr 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 229' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-04-24T13:56:53-04:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '45e19495-93bf-4b97-b734-dd516adcb503' | System | 24 Apr 2021 17:57:06 |
| User entered 'No (N)' | System | 24 Apr 2021 17:57:06 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

Have you been exposed to someone with 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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-04-24T13:56:58-04:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '45e19495-93bf-4b97-b734-dd516adcb503' | System | 24 Apr 2021 17:57:06 |
| User entered 'No (N)' | System | 24 Apr 2021 17:57:06 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-04-24T13:57:01-04:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '45e19495-93bf-4b97-b734-dd516adcb503' | System | 24 Apr 2021 17:57:06 |
| User entered '24 Apr 2021 13:57:01' | System | 24 Apr 2021 17:57:06 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '24 Apr 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '28 Apr 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 236' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-05-01T06:57:36-05:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'db05593e-8674-447b-be82-bf8e26aaa2aa' | System | 01 May 2021 11:57:56 |
| User entered 'No (N)' | System | 01 May 2021 11:57:56 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

Have you been exposed to someone with 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 (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-05-01T06:57:48-05:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'db05593e-8674-447b-be82-bf8e26aaa2aa' | System | 01 May 2021 11:57:56 |
| User entered 'No (N)' | System | 01 May 2021 11:57:56 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-05-01T06:57:53-05:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: 'db05593e-8674-447b-be82-bf8e26aaa2aa' | System | 01 May 2021 11:57:56 |
| User entered '01 May 2021 06:57:53' | System | 01 May 2021 11:57:56 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '01 May 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '05 May 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 243' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '08 May 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '12 May 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 250' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '15 May 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '19 May 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 257' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '22 May 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '26 May 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 264' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '29 May 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '02 Jun 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 271' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '05 Jun 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '09 Jun 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 278' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '12 Jun 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '16 Jun 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 285' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '19 Jun 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '23 Jun 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 292' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '26 Jun 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '30 Jun 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 299' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '03 Jul 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '07 Jul 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 306' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '10 Jul 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '14 Jul 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 313' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '17 Jul 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '21 Jul 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 320' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '24 Jul 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '28 Jul 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 327' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '31 Jul 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '04 Aug 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 334' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '07 Aug 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '11 Aug 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 341' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '14 Aug 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '18 Aug 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 348' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '21 Aug 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '25 Aug 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 355' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '28 Aug 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '01 Sep 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 362' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '04 Sep 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '08 Sep 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 369' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '11 Sep 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '15 Sep 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 376' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '18 Sep 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '22 Sep 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 383' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '25 Sep 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '29 Sep 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 390' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '02 Oct 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '06 Oct 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 397' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '09 Oct 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '13 Oct 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 404' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '16 Oct 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '20 Oct 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 411' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '23 Oct 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '27 Oct 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 418' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '30 Oct 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '03 Nov 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 425' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '06 Nov 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '10 Nov 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 432' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '13 Nov 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '17 Nov 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 439' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '20 Nov 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '24 Nov 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 446' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '27 Nov 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '01 Dec 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 453' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '04 Dec 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '08 Dec 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 460' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '11 Dec 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '15 Dec 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 467' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '18 Dec 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '22 Dec 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 474' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '25 Dec 2021 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '29 Dec 2021 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 481' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '01 Jan 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '05 Jan 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 488' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '08 Jan 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '12 Jan 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 495' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '15 Jan 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '19 Jan 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 502' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '22 Jan 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '26 Jan 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 509' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '29 Jan 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '02 Feb 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 516' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '05 Feb 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '09 Feb 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 523' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '12 Feb 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '16 Feb 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 530' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '19 Feb 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '23 Feb 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 537' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '26 Feb 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '02 Mar 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 544' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '05 Mar 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '09 Mar 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 551' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '12 Mar 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '16 Mar 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 558' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '19 Mar 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '23 Mar 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 565' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '26 Mar 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '30 Mar 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 572' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '02 Apr 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '06 Apr 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 579' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '09 Apr 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '13 Apr 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 586' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '16 Apr 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '20 Apr 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 593' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '23 Apr 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '27 Apr 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 600' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '30 Apr 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '04 May 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 607' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '07 May 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '11 May 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 614' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '14 May 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '18 May 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 621' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '21 May 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '25 May 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 628' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '28 May 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '01 Jun 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 635' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '04 Jun 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '08 Jun 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 642' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '11 Jun 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '15 Jun 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 649' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '18 Jun 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '22 Jun 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 656' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '25 Jun 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '29 Jun 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 663' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '02 Jul 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '06 Jul 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 670' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '09 Jul 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '13 Jul 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 677' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '16 Jul 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '20 Jul 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 684' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '23 Jul 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '27 Jul 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 691' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '30 Jul 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '03 Aug 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 698' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '06 Aug 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '10 Aug 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 705' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '13 Aug 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '17 Aug 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 712' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '20 Aug 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '24 Aug 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 719' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '27 Aug 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '31 Aug 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 726' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '03 Sep 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '07 Sep 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 733' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '10 Sep 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '14 Sep 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 740' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '17 Sep 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '21 Sep 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 747' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '24 Sep 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '28 Sep 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 754' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '01 Oct 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '05 Oct 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 761' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '08 Oct 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '12 Oct 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 768' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '15 Oct 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '19 Oct 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 775' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '22 Oct 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '26 Oct 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 782' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '29 Oct 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '02 Nov 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 789' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '05 Nov 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '09 Nov 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered 'Day 796' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '12 Nov 2022 00:01' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:56

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 07:12:13 |
| Amendment Manager: User entered '16 Nov 2022 23:59' | System | 20 Nov 2020 07:12:13 |

US3532281

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:09:56

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) | 24 Apr 2021 10:15:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-02-27T09:30:38-05:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '71994456-07b7-4cd6-82f7-af4f72c1b8f9' | System | 27 Feb 2021 14:32:13 |
| User entered 'Yes (Y)' | System | 27 Feb 2021 14:32:13 |

US3532281

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:09:56

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?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:15:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-02-27T09:31:01-05:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '71994456-07b7-4cd6-82f7-af4f72c1b8f9' | System | 27 Feb 2021 14:32:13 |
| User entered 'Yes (Y)' | System | 27 Feb 2021 14:32:13 |

US3532281

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:09:56

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:15:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6803C3-40BA-4463-AB4D-2EE61078BF6E)', Time: '2021-02-27T09:31:39-05:00', User OID: 'PatientReportedOutcome (US3532281)', ODM File OID: '71994456-07b7-4cd6-82f7-af4f72c1b8f9' User entered '27 Feb 2021 14:31:39' | System | 27 Feb 2021 14:32:13 |
| | System | 27 Feb 2021 14:32:13 |

US3532281

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 25 Mar 2021 17:46:21 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 30 Nov 2020 19:48:01 |

US3532281

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 25 Mar 2021 17:46:21 |
| User entered '30 Nov 2020' | Cindy Lubbers (b) (4) | 30 Nov 2020 19:48:01 |

US3532281

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 25 Mar 2021 17:46:21 |
| User entered 'Contact Made (CONTACT MADE)' | Cindy Lubbers (b) (4) | 30 Nov 2020 19:48:01 |

US3532281

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 25 Mar 2021 17:46:21 |
| User entered empty. | Cindy Lubbers (b) (4) | 30 Nov 2020 19:48:01 |

US3532281

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 25 Mar 2021 17:46:21 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 30 Nov 2020 19:48:06 |

US3532281

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:46:09 |
| User entered 'I' | System | 30 Nov 2020 19:48:06 |

US3532281

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 04 Jan 2021 14:26:22 |

US3532281

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '31 Dec 2020' | Cindy Lubbers (b) (4) | 04 Jan 2021 14:26:22 |

US3532281

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Contact Made (CONTACT MADE)' | Cindy Lubbers (b) (4) | 04 Jan 2021 14:26:22 |

US3532281

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered empty. | Cindy Lubbers (b) (4) | 04 Jan 2021 14:26:22 |

US3532281

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 04 Jan 2021 14:26:27 |

US3532281

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User entered 'I' | System | 04 Jan 2021 14:26:27 |

US3532281

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 03 Feb 2021 20:37:33 |

US3532281

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '3 Feb 2021' | Cindy Lubbers (b) (4) | 03 Feb 2021 20:37:33 |

US3532281

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Contact Made (CONTACT MADE)' | Cindy Lubbers (b) (4) | 03 Feb 2021 20:37:33 |

US3532281

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered empty. | Cindy Lubbers (b) (4) | 03 Feb 2021 20:37:33 |

US3532281

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 03 Feb 2021 20:37:38 |

US3532281

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User entered 'I' | System | 03 Feb 2021 20:37:38 |

US3532281

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 02 Mar 2021 15:21:20 |

US3532281

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '2 Mar 2021' | Cindy Lubbers (b) (4) | 02 Mar 2021 15:21:20 |

US3532281

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Contact Made (CONTACT MADE)' | Cindy Lubbers (b) (4) | 02 Mar 2021 15:21:20 |

US3532281

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:56

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered empty. | Cindy Lubbers (b) (4) | 02 Mar 2021 15:21:20 |

US3532281

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 02 Mar 2021 15:21:25 |

US3532281

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User entered 'I' | System | 02 Mar 2021 15:21:25 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:56

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 24 Mar 2021 19:56:01 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '24 Mar 2021' | Cindy Lubbers (b) (4) | 24 Mar 2021 19:56:01 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Clinic (Clinic)' | Cindy Lubbers (b) (4) | 24 Mar 2021 19:56:01 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:56

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User entered 'VISIT4' | System | 24 Mar 2021 19:56:01 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'No (N)' | Laila Hussaini (b) (4) | 01 Apr 2021 19:05:16 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered empty. | Laila Hussaini (b) (4) | 01 Apr 2021 19:05:16 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered empty. | Laila Hussaini (b) (4) | 01 Apr 2021 19:05:16 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User entered empty. | System | 01 Apr 2021 19:05:16 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered empty. | Laila Hussaini (b) (4) | 01 Apr 2021 19:05:16 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered empty. | Laila Hussaini (b) (4) | 01 Apr 2021 19:05:16 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered empty. | Laila Hussaini (b) (4) | 01 Apr 2021 19:05:16 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered empty. | Laila Hussaini (b) (4) | 01 Apr 2021 19:05:16 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User entered empty. | System | 01 Apr 2021 19:05:16 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered empty. | Laila Hussaini (b) (4) | 01 Apr 2021 19:05:16 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User entered empty. | System | 01 Apr 2021 19:05:16 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered empty. | Laila Hussaini (b) (4) | 01 Apr 2021 19:05:16 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User entered empty. | System | 01 Apr 2021 19:05:16 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered empty. | Laila Hussaini (b) (4) | 01 Apr 2021 19:05:16 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User entered empty. | System | 01 Apr 2021 19:05:16 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

Height (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| | | |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:56

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| | | |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:56

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 24 Mar 2021 19:56:18 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:56

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered empty. | Cindy Lubbers (b) (4) | 24 Mar 2021 19:56:18 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:56

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 24 Mar 2021 19:59:16 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:56

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '24 Mar 2021' | Cindy Lubbers (b) (4) | 24 Mar 2021 19:59:16 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:56

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '14:55' | Cindy Lubbers (b) (4) | 24 Mar 2021 19:59:16 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:56

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User entered '24 Mar 2021 14:55' | System | 24 Mar 2021 19:59:16 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 24 Mar 2021 19:59:20 |

US3532281

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:56

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:47:09 |
| User entered 'I' | System | 24 Mar 2021 19:59:20 |

US3532281

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

Form: Visit Date

Generated On: 10 Jun 2021 08:09:56

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Yes (Y)' | Teresa Ball (b) (4) | 12 Jan 2021 17:30:00 |

US3532281

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

Form: Visit Date

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '12 Jan 2021' | Teresa Ball (b) (4) | 12 Jan 2021 17:30:00 |

US3532281

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

Form: Visit Date

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Clinic (Clinic)' | Teresa Ball (b) (4) | 12 Jan 2021 17:30:00 |

US3532281

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

Form: Visit Date

Generated On: 10 Jun 2021 08:09:56

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered 'UNBLND_DECIDE' | System | 12 Jan 2021 17:30:00 |

US3532281

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

Form: Unblinding

Generated On: 10 Jun 2021 08:09:56

Date of updated informed consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '12 Jan 2021' | Teresa Ball (b) (4) | 12 Jan 2021 17:30:24 |

US3532281

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

Form: Unblinding

Generated On: 10 Jun 2021 08:09:56

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '0' WR# 5295537 | (b) (4) | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 08:47:31 |

US3532281

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

Form: Unblinding

Generated On: 10 Jun 2021 08:09:56

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Yes (Y)' | Teresa Ball (b) (4) | 12 Jan 2021 17:30:24 |

US3532281

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

Form: Unblinding

Generated On: 10 Jun 2021 08:09:56

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| 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 08:47:31 |

US3532281

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

Form: Unblinding

Generated On: 10 Jun 2021 08:09:56

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '12 Jan 2021' | Teresa Ball (b) (4) | 12 Jan 2021 17:30:24 |

US3532281

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

Form: Unblinding

Generated On: 10 Jun 2021 08:09:56

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'mRNA-1273 (mRNA-1273)' | Teresa Ball (b) (4) | 12 Jan 2021 17:30:24 |

US3532281

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

Form: Unblinding

Generated On: 10 Jun 2021 08:09:56

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)' | (b) (4) | 20 Jan 2021 04:33:02 |
| User entered 'mRNA-1273 (mRNA-1273)' | Teresa Ball (b) (4) | 12 Jan 2021 17:30:24 |
| | (b) (4) | |

US3532281

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

Form: Unblinding

Generated On: 10 Jun 2021 08:09:56

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)' | (b) (4) | 20 Jan 2021 04:33:02 |
| User entered 'mRNA-1273 (mRNA-1273)' | Teresa Ball (b) (4) | 12 Jan 2021 17:30:24 |
| | (b) (4) | |

US3532281

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

Form: Unblinding

Generated On: 10 Jun 2021 08:09:56

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'No (N)' | Teresa Ball (b) (4) | 12 Jan 2021 17:30:24 |

US3532281

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

Form: Unblinding

Generated On: 10 Jun 2021 08:09:56

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered empty. | System | 12 Jan 2021 17:30:24 |

US3532281

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

Form: Unblinding

Generated On: 10 Jun 2021 08:09:56

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered empty. | System | 12 Jan 2021 17:30:24 |

US3532281

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:56

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Yes (Y)' | Teresa Ball (b) (4) | 12 Jan 2021 17:30:59 |

US3532281

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:56

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '12 Jan 2021' | Teresa Ball (b) (4) | 12 Jan 2021 17:30:59 |

US3532281

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:56

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '11:54' | Teresa Ball (b) (4) | 12 Jan 2021 17:30:59 |

US3532281

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:56

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '12 Jan 2021 11:54' | System | 12 Jan 2021 17:30:59 |

US3532281

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:09:56

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Yes (Y)' | Teresa Ball (b) (4) | 12 Jan 2021 17:31:14 |

US3532281

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:09:56

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '12 Jan 2021' | Teresa Ball (b) (4) | 12 Jan 2021 17:31:14 |

US3532281

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:09:56

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '11:43' | Teresa Ball (b) (4) | 12 Jan 2021 17:31:14 |

US3532281

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:09:56

[Collection Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:37:43 |
| User entered '12 Jan 2021 11:43' | System | 12 Jan 2021 17:31:14 |

US3532281

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:09:56

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:42:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:21 |
| User signature succeeded. | Evan Anderson (b) (4) | 19 Mar 2021 09:18:50 |
| User entered 'Yes (Y)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 27 Oct 2020 17:44:51 |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| | | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | (b) (4) | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Epistaxis, LLT: Nosebleed - version MedDRA\23.0. | Coder Import (b) (4) | 27 Oct 2020 17:47:34 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 27 Oct 2020 17:47:34 |
| | (b) (4) | |
| Data point term sent to Coder | System | 27 Oct 2020 17:46:51 |
| User entered 'NOSEBLEED' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 27 Oct 2020 17:46:14 |
| | (b) (4) | |
| User entered 'Nosebleeds' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 27 Oct 2020 17:46:14 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 27 Oct 2020 17:46:14 |
| User entered 'No (N)' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 27 Oct 2020 17:46:14 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 27 Oct 2020 17:45:57 |
| User entered empty. | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered '10 Oct 2020' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User entered empty. | System | 27 Oct 2020 17:45:57 |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

If not Ongoing, end date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered '10 Oct 2020' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User entered empty. | System | 27 Oct 2020 17:45:57 |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[Severity](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered '0' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered '0' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered '0' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered '0' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered '0' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered '0' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Related (RELATED)' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'None (NONE)' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

None

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'I' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered '0' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered '0' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[Outcome](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 27 Oct 2020 17:45:57 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User entered '0' | System | 27 Oct 2020 17:45:57 |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| User entered '0' | System | 27 Oct 2020 17:46:14 |

US3532281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:09:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:33 |
| | | |
| | | |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[AEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) | 25 Mar 2021 18:27:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 17:08:49 |
| User entered | (b) (4), (b) (6) | 28 Oct 2020 17:08:44 |
| 'USA-US077-2020-mRNA-1273-P301000006' | System | 28 Oct 2020 17:08:44 |
| User entered 'New' | (b) (4), (b) (6) | 28 Oct 2020 17:08:44 |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|--|--|
| User signature succeeded. | Evan Anderson (b) (4) | 16 Apr 2021 08:40:02 |
| User closed query 'PV Query: The event term LEFT ANKLE PAIN- WORSENING OF OSTEOARTHRITIS contains multiple event terms. Please consider separating them into separate events. ' (Site from Safety). DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Apr 2021 19:09:52 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis aggravated - version MedDRA\\23.0. User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. Data point term sent to Coder Query 'PV Query: The event term LEFT ANKLE PAIN- WORSENING OF OSTEOARTHRITIS contains multiple event terms. Please consider separating them into separate events. ' answered with 'Changed to worsening of osteoarthritis' (Site from Safety). DataPoint Un-verified. | (b) (4), (b) (6) Coder Import (b) (4) (b) (4) Coder Import (b) (4) (b) (4) System Cindy Lubbers (b) (4) (b) (4) Cindy Lubbers (b) (4) (b) (4) Cindy Lubbers (b) (4) (b) (4) | 09 Apr 2021 14:20:12 09 Apr 2021 13:23:46 09 Apr 2021 13:23:46 09 Apr 2021 13:22:36 09 Apr 2021 13:22:12 09 Apr 2021 13:21:56 |
| Coding entries removed. | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 09 Apr 2021 13:21:56 |
| Signature has been broken. | Cindy Lubbers (b) (4) (b) (4) Cindy Lubbers (b) (4) (b) (4) | 09 Apr 2021 13:21:56 |
| User entered 'WORSENING OF OSTEOARTHRITIS' reason for change: Per Query Resolution | Cindy Lubbers (b) (4) (b) (4) | 09 Apr 2021 13:21:56 |
| User opened query 'PV Query: The event term LEFT ANKLE PAIN- WORSENING OF OSTEOARTHRITIS contains multiple event terms. Please consider separating them into separate events. ' (Site from Safety). | (b) (4), (b) (6) | 08 Apr 2021 13:02:28 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Ankle osteoarthritis - version MedDRA\\23.0. User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) Coder Import (b) (4) (b) (4) | 06 Apr 2021 12:26:56 06 Apr 2021 12:26:56 |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User closed query ' per DS it was worsening of left ankle arthritis so please update term to "Left Ankle pain - worsening of osteoarthritis" ' (Site from CRA). | (b) (4), (b) (6) | 02 Apr 2021 21:50:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 21:50:22 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Query ' per DS it was worsening of left ankle arthritis so please update term to "Left Ankle pain - worsening of osteoarthritis" ' answered with 'completed' (Site from CRA). | Cindy Lubbers (b) (4) | 31 Mar 2021 13:40:48 |
| Data point term sent to Coder | System | 31 Mar 2021 13:39:33 |
| DataPoint Un-verified. | Cindy Lubbers (b) (4) | 31 Mar 2021 13:38:44 |
| Coding entries removed. | Cindy Lubbers (b) (4) | 31 Mar 2021 13:38:44 |
| User entered 'Left ankle pain- worsening of osteoarthritis' reason for change: Per Query Resolution | Cindy Lubbers (b) (4) | 31 Mar 2021 13:38:44 |
| User opened query ' per DS it was worsening of left ankle arthritis so please update term to "Left Ankle pain - worsening of osteoarthritis" ' (Site from CRA). | (b) (4), (b) (6) | 25 Mar 2021 19:23:40 |
| Query 'per DS it was worsening of left ankle arthritis so please update term to "Left Ankle pain - worsening of arthritis"' canceled (Site from CRA). | (b) (4), (b) (6) | 25 Mar 2021 19:23:09 |
| User opened query 'per DS it was worsening of left ankle arthritis so please update term to "Left Ankle pain - worsening of arthritis"' (Site from CRA). | (b) (4), (b) (6) | 25 Mar 2021 19:18:51 |
| User closed query 'AE source log = Left Ankle Replacement for Worsening Pain, please reconcile' (Site from CRA). | (b) (4), (b) (6) | 25 Mar 2021 19:15:33 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Mar 2021 18:27:30 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in ankle - version MedDRA\23.0. | Coder Import (b) (4) | 05 Mar 2021 22:49:59 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 05 Mar 2021 22:49:59 |
| Data point term sent to Coder | System | 05 Mar 2021 17:44:50 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User entered 'Acute left ankle pain' reason for change: Per Query Resolution | Cindy Lubbers (b) (4) | 05 Mar 2021 17:44:44 |
| Data point term sent to Coder | (b) (4) | |
| Query 'AE source log = Left Ankle Replacement for Worsening Pain, please reconcile' answered with 'Corrected' (Site from CRA). | System | 05 Mar 2021 15:04:45 |
| Coding entries removed. | Cindy Lubbers (b) (4) | 05 Mar 2021 15:04:02 |
| | (b) (4) | |
| User entered 'Left Ankle Replacement for Worsening Pain' reason for change: Per Query Resolution | Cindy Lubbers (b) (4) | 05 Mar 2021 15:03:54 |
| | (b) (4) | |
| User opened query 'AE source log = Left Ankle Replacement for Worsening Pain, please reconcile' (Site from CRA). | (b) (4), (b) (6) | 04 Mar 2021 20:53:57 |
| User closed query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Fifth Metatarsal Break. If yes, please update to reflect the term worsening as appropriate and ensure that Severity is greater than Grade 1/ Mild. Please update applicable details as appropriate or provide clarification.' (Site from DM). | (b) (4), (b) (6) | 08 Feb 2021 09:40:02 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Fracture pain, LLT: Fracture pain - version MedDRA\23.0. | Coder Import (b) (4) | 07 Feb 2021 17:01:41 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 07 Feb 2021 17:01:41 |
| Query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Fifth Metatarsal Break. If yes, please update to reflect the term worsening as appropriate and ensure that Severity is greater than Grade 1/ Mild. Please update applicable details as appropriate or provide clarification.' answered with 'corrected' (Site from DM). | Cindy Lubbers (b) (4) | 05 Feb 2021 14:55:04 |
| | (b) (4) | |
| Data point term sent to Coder | System | 05 Feb 2021 14:54:59 |
| User entered 'LEFT ANKLE WORSENING PAIN from 5th metatarsal break' reason for change: Per Query Resolution | Cindy Lubbers (b) (4) | 05 Feb 2021 14:54:55 |
| | (b) (4) | |
| Data point term sent to Coder | System | 03 Feb 2021 20:45:09 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Coding entries removed. | Cindy Lubbers (b) (4) | 03 Feb 2021 20:44:37 |
| | (b) (4) | |
| User entered 'LEFT ANKLE WORSENING PAIN' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 03 Feb 2021 20:44:37 |
| | (b) (4) | |
| User opened query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Fifth Metatarsal Break. If yes, please update to reflect the term worsening as appropriate and ensure that Severity is greater than Grade 1/ Mild. Please update applicable details as appropriate or provide clarification.' (Site from DM). | (b) (4), (b) (6) | 03 Feb 2021 20:20:48 |
| | | |
| User closed query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate. Please ensure the surgery/procedure is recorded on the Con Proc eCRF.' (Site from DM). | (b) (4), (b) (6) | 06 Jan 2021 06:55:50 |
| | | |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Foot fracture, LLT: Foot fracture - version MedDRA\23.0. | Coder Import (b) (4) | 05 Jan 2021 14:10:43 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 05 Jan 2021 14:10:43 |
| | (b) (4) | |
| Data point term sent to Coder | System | 05 Jan 2021 13:41:31 |
| Query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate. Please ensure the surgery/procedure is recorded on the Con Proc eCRF.' answered with 'done' (Site from DM). | Cindy Lubbers (b) (4) | 05 Jan 2021 13:41:04 |
| | (b) (4) | |
| Coding entries removed. | Cindy Lubbers (b) (4) | 05 Jan 2021 13:40:56 |
| | (b) (4) | |
| User entered 'LEFT ANKLE WORSENING PAIN - 5TH METATARSAL BREAK' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 05 Jan 2021 13:40:56 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User opened query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate. Please ensure the surgery/procedure is recorded on the Con Proc eCRF. ' (Site from DM). | (b) (4), (b) (6) | 26 Dec 2020 03:23:39 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Foot fracture, LLT: Foot fracture - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Dec 2020 18:44:50 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Dec 2020 18:44:50 |
| User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event (possibly 5th metatarsal break).' (Site from Safety). | (b) (4), (b) (6) | 01 Dec 2020 15:29:39 |
| Data point term sent to Coder | System | 30 Nov 2020 19:47:23 |
| Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event (possibly 5th metatarsal break).' answered with 'done' (Site from Safety). | Cindy Lubbers (b) (4) | 30 Nov 2020 19:47:14 |
| Coding entries removed. | Cindy Lubbers (b) (4) | 30 Nov 2020 19:47:08 |
| User entered 'LEFT ANKLE REPLACEMENT-5th metatarsal break' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 30 Nov 2020 19:47:08 |
| User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event (possibly 5th metatarsal break).' (Site from Safety). | (b) (4), (b) (6) | 25 Nov 2020 14:05:05 |
| User coded data point as SOC: Surgical and medical procedures, HLT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Ankle arthroplasty, LLT: Ankle reconstruction - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Oct 2020 17:51:30 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Oct 2020 17:51:30 |
| Data point term sent to Coder | System | 27 Oct 2020 17:49:55 |
| User entered 'Left ankle replacement' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:49:49 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:01:17 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) (b) (4) | 27 Oct 2020 17:49:49 |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:01:18 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) (b) (4) | 27 Oct 2020 17:49:49 |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:01:20 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) (b) (4) | 27 Oct 2020 17:49:49 |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User closed query 'please confirm the AE start date from the worsening pain' (Site from CRA). | (b) (4), (b) (6) | 02 Apr 2021 21:51:54 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User closed query 'PV Query: Please clarify the event start and stop dates which are reported on the same date of 23Oct2020, considering that hospitalization of more than 24 hours is needed to meet the seriousness criteria of hospitalization. ' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 01 Apr 2021 14:22:50 |
| Query 'PV Query: Please clarify the event start and stop dates which are reported on the same date of 23Oct2020, considering that hospitalization of more than 24 hours is needed to meet the seriousness criteria of hospitalization. ' answered with 'corrected' (Site from Safety). | Cindy Lubbers (b) (4) (b) (4) | 31 Mar 2021 13:52:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Mar 2021 18:27:30 |
| User opened query 'PV Query: Please clarify the event start and stop dates which are reported on the same date of 23Oct2020, considering that hospitalization of more than 24 hours is needed to meet the seriousness criteria of hospitalization. ' (Site from Safety). | (b) (4), (b) (6) | 12 Mar 2021 15:39:14 |
| Query 'please confirm the AE start date from the worsening pain' answered with 'Corrected' (Site from CRA). | Cindy Lubbers (b) (4) (b) (4) | 05 Mar 2021 18:17:00 |
| User closed query 'Adverse Event Start Date is before System treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System). | | 05 Mar 2021 18:16:23 |
| User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System). | System | 05 Mar 2021 18:16:23 |
| User entered '23 Oct 2020' reason for change: Data Entry Error | Cindy Lubbers (b) (4) (b) (4) | 05 Mar 2021 18:16:23 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' <p>(Site from System).</p> | System | 05 Mar 2021 18:13:31 |
| User opened query 'The Start Date for Adverse Event System is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System). | | 05 Mar 2021 18:13:31 |
| User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' <p>(Site from System).</p> | System | 05 Mar 2021 18:13:31 |
| User closed query 'The Start Date for Adverse Event System is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System). | | 05 Mar 2021 18:13:31 |
| User entered '23 Aug 2020' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 05 Mar 2021 18:13:31 |
| User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' <p>(Site from System).</p> | (b) (4) System | 05 Mar 2021 17:44:44 |
| User opened query 'The Start Date for Adverse Event System is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System). | | 05 Mar 2021 17:44:44 |
| User entered '31 Aug 2020' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 05 Mar 2021 17:44:44 |
| User opened query 'please confirm the AE start date from the worsening pain' (Site from CRA). | (b) (4), (b) (6) | 04 Mar 2021 21:06:06 |
| User entered '23 Oct 2020' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:49:49 |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Mar 2021 18:27:30 |
| User entered empty. | Cindy Lubbers (b) (4) (b) (4) | 27 Oct 2020 17:49:49 |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Oct 2020 17:49:49 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Mar 2021 18:27:30 |
| User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). | System | 06 Nov 2020 21:49:43 |
| User entered 'No (N)' reason for change: Data Entry Error | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 21:49:43 |
| User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). | System | 06 Nov 2020 21:49:01 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Cindy Lubbers (b) (4) (b) (4) | 27 Oct 2020 17:50:20 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) (b) (4) | 27 Oct 2020 17:49:49 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 21:52:22 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Un-verified. | Cindy Lubbers (b) (4) | 31 Mar 2021 13:50:08 |
| User entered '25 Oct 2020' reason for change: Per Query Resolution | Cindy Lubbers (b) (4) | 31 Mar 2021 13:50:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Mar 2021 18:27:30 |
| User entered '23 Oct 2020' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 03 Feb 2021 20:43:07 |
| User entered '25 Oct 2020' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 17 Nov 2020 14:20:32 |
| User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | (b) (4), (b) (6) | 09 Nov 2020 18:57:00 |
| User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | (b) (4), (b) (6) | 09 Nov 2020 10:46:17 |
| Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'done' (Site from System). | Cindy Lubbers (b) (4) | 06 Nov 2020 21:49:51 |
| 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 'done' (Site from Safety). | Cindy Lubbers (b) (4) | 06 Nov 2020 21:49:21 |
| User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | System | 06 Nov 2020 21:49:01 |
| User entered '23 Oct 2020' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 06 Nov 2020 21:49:01 |
| 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) | 06 Nov 2020 16:54:37 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System). | System | 27 Oct 2020 17:50:20 |
| User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System). | System | 27 Oct 2020 17:49:49 |
| User entered empty. | Cindy Lubbers (b) (4) (b) (4) | 27 Oct 2020 17:49:49 |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:20:00 |
| User entered empty. | Cindy Lubbers (b) (4) (b) (4) | 27 Oct 2020 17:49:49 |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Oct 2020 17:49:49 |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Severity](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 04 Mar 2021 21:19:57 |
| User entered 'Grade 4 (Grade 4)' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:49:49 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:19:58 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) (b) (4) | 27 Oct 2020 17:49:49 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 04 Mar 2021 21:01:39 |
| User entered '0' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:49:49 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 04 Mar 2021 21:01:40 |
| User entered '0' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:49:49 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:01:42 |
| User entered 'I' | Cindy Lubbers (b) (4) (b) (4) | 27 Oct 2020 17:49:49 |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 04 Mar 2021 21:01:44 |
| User entered '23 Oct 2020' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:49:49 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:01:47 |
| User entered '25 Oct 2020' | Cindy Lubbers (b) (4) (b) (4) | 27 Oct 2020 17:49:49 |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:01:48 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) (b) (4) | 27 Oct 2020 17:49:49 |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:01:50 |
| User entered empty. | Cindy Lubbers (b) (4) (b) (4) | 27 Oct 2020 17:49:49 |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 04 Mar 2021 21:01:53 |
| User entered '0' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:49:49 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:01:55 |
| User entered '0' | Cindy Lubbers (b) (4) (b) (4) | 27 Oct 2020 17:49:49 |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 04 Mar 2021 21:01:57 |
| User entered '0' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:49:49 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:01:58 |
| User entered 'Not Related (NOT RELATED)' | Cindy Lubbers (b) (4) (b) (4) | 27 Oct 2020 17:49:49 |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 04 Mar 2021 21:02:00 |
| User entered 'Not Related (NOT RELATED)' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:49:49 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

Action taken with investigational product

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:02:03 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 27 Oct 2020 17:50:20 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 27 Oct 2020 17:50:20 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error | Cindy Lubbers (b) (4) (b) (4) | 27 Oct 2020 17:50:20 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 27 Oct 2020 17:49:49 |
| User entered empty. | Cindy Lubbers (b) (4) (b) (4) | 27 Oct 2020 17:49:49 |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 04 Mar 2021 21:02:07 |
| User entered '0' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:49:49 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:02:10 |
| User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'Meds are listed as starting on Oct 23rd- these are the meds for this AE' (Site from DM). | (b) (4), (b) (6) | 05 Feb 2021 02:48:32 |
| Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the the ConMed treatment as appropriate. Otherwise, clarify.' | Cindy Lubbers (b) (4) (b) (4) | 03 Feb 2021 20:52:15 |
| User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 03 Feb 2021 20:20:58 |
| User entered 'I' | Cindy Lubbers (b) (4) (b) (4) | 27 Oct 2020 17:49:49 |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:02:12 |
| User closed query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure is not indicated for an AE. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 05 Feb 2021 02:48:37 |
| Query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure is not indicated for an AE. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' answered with 'Surgery is listed in con procedures' (Site from DM). | Cindy Lubbers (b) (4) (b) (4) | 03 Feb 2021 20:53:17 |
| User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure is not indicated for an AE. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 03 Feb 2021 20:21:07 |
| User entered 'I' | Cindy Lubbers (b) (4) (b) (4) | 27 Oct 2020 17:49:49 |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Outcome](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User closed query 'please verify if confirmed by source (AE Log)' (Site from CRA). | (b) (4), (b) (6) | 12 Apr 2021 15:58:22 |
| Query 'please verify if confirmed by source (AE Log)' answered with 'confirmed' (Site from CRA). | Cindy Lubbers (b) (4) | 09 Apr 2021 19:58:23 |
| User opened query 'please verify if confirmed by source (AE Log)' (Site from CRA). | (b) (4), (b) (6) | 09 Apr 2021 14:21:10 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:03:30 |
| User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4), (b) (6) | 09 Nov 2020 18:57:05 |
| Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'done' (Site from Safety). | Cindy Lubbers (b) (4) | 06 Nov 2020 21:50:29 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 06 Nov 2020 21:50:20 |
| User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4), (b) (6) | 06 Nov 2020 16:55:04 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:49:49 |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:03:32 |
| User entered empty. | Cindy Lubbers (b) (4) (b) (4) | 27 Oct 2020 17:49:49 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Narrative](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 21:52:52 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User closed query 'PV Query: Left total ankle arthroplasty was previously reported to have been on 23 Oct 2020, but the newest case narrative stated it occurred on 12 Oct 2020. Please confirm the date of surgery. ' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 01 Apr 2021 14:22:56 |
| Query 'PV Query: Left total ankle arthroplasty was previously reported to have been on 23 Oct 2020, but the newest case narrative stated it occurred on 12 Oct 2020. Please confirm the date of surgery. ' answered with 'Corrected' (Site from Safety). | Cindy Lubbers (b) (4) (b) (4) | 31 Mar 2021 14:00:09 |
| User entered 'SUBJECT HAS OSTEOARTHRITIS IN THE LEFT ANKLE THAT HAS BEEN WORSENING, subject OPTED FOR ANKLE REPLACEMENT SURGERY, WHICH WAS PERFORMED ON 23OCT2020.PER SUBJECT, SURGERY HAD BEEN PLANNED IN JUNE BUT HE WITHHELD DUE TO COVID. ADDED AS AE BECAUSE REQUIRED HOSPITALIZATION OVER 24 HOURS.' reason for change: Per Query Resolution | Cindy Lubbers (b) (4) (b) (4) | 31 Mar 2021 13:58:32 |
| DataPoint Un-verified. | Cindy Lubbers (b) (4) (b) (4) | 31 Mar 2021 13:38:44 |
| User entered 'SUBJECT HAS OSTEOARTHRITIS IN THE LEFT ANKLE THAT HAS BEEN WORSENING, AND WORSENERED MORE WITH 5TH METATARSAL FRACTURE, WHICH WAS TREATED WITH BOOT THERAPY. WITH THE WORSENING PAIN, SUBJECT OPTED FOR ANKLE REPLACEMENT SURGERY, WHICH WAS PERFORMED ON 23OCT2020.PER SUBJECT, SURGERY HAD BEEN PLANNED IN JUNE BUT HE WITHHELD DUE TO COVID. ADDED AS AE BECAUSE REQUIRED HOSPITALIZATION OVER 24 HOURS.' reason for change: Per Query Resolution | Cindy Lubbers (b) (4) (b) (4) | 31 Mar 2021 13:38:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Mar 2021 18:27:30 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Narrative](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User opened query 'PV Query: Left total ankle arthroplasty was previously reported to have been on 23 Oct 2020, but the newest case narrative stated it occurred on 12 Oct 2020. Please confirm the date of surgery. ' (Site from Safety). | (b) (4), (b) (6) | 12 Mar 2021 15:39:33 |
| User entered 'SUBJECT HAS OSTEOARTHRITIS IN THE LEFT ANKLE THAT HAS BEEN WORSENING, AND WORSENERED MORE WITH 5TH METATARSAL FRACTURE, WHICH WAS TREATED WITH BOOT THERAPY. WITH THE WORSENING PAIN, SUBJECT OPTED FOR ANKLE REPLACEMENT SURGERY, WHICH WAS PERFORMED ON 12OCT2020.per subject, surgery had been planned in June but he withheld due to COVID. Added as AE because required hospitalization over 24 hours.' reason for change: Per Query Resolution | Cindy Lubbers (b) (4) | 05 Mar 2021 18:16:23 |
| User entered 'Subject has osteoarthritis in the left ankle that has been worsening, and worsened more with 5th metatarsal fracture, which was treated with boot therapy. With the worsening pain, subject opted for ankle replacement surgery, which was performed on 12OCT2020.' reason for change: Per Query Resolution | Cindy Lubbers (b) (4) | 05 Mar 2021 17:44:44 |
| User closed query 'PV Query: Event end date is the same as start date. Please provide reason the subject remained hospitalized after event resolved. Please report additional events if required. ' (Site from Safety). | (b) (4), (b) (6) | 18 Nov 2020 16:23:56 |
| User closed query 'PV Query: Documents not received. Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety). | (b) (4), (b) (6) | 18 Nov 2020 16:23:49 |
| Query 'PV Query: Event end date is the same as start date. Please provide reason the subject remained hospitalized after event resolved. Please report additional events if required. ' answered with 'corrected' (Site from Safety). | Cindy Lubbers (b) (4) | 17 Nov 2020 14:37:10 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Narrative](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Query 'PV Query: Documents not received. Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Discharge records emailed 17NOV2020@ 0935' (Site from Safety). | Cindy Lubbers (b) (4) (b) (4) | 17 Nov 2020 14:37:03 |
| User opened query 'PV Query: Event end date is the same as start date. Please provide reason the subject remained hospitalized after event resolved. Please report additional events if required. ' (Site from Safety). | (b) (4), (b) (6) | 16 Nov 2020 19:28:40 |
| User opened query 'PV Query: Documents not received. Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety). | (b) (4), (b) (6) | 16 Nov 2020 19:27:58 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 09 Nov 2020 18:57:28 |
| 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) | 09 Nov 2020 18:57:26 |
| User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety). | (b) (4), (b) (6) | 09 Nov 2020 18:57:18 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Narrative](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6) | 09 Nov 2020 18:56:48 |
| Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'emailed 06nov2020' (Site from Safety). | Cindy Lubbers (b) (4) | 06 Nov 2020 22:01:35 |
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'No record of COVID test in medical records' (Site from Safety). | Cindy Lubbers (b) (4) | 06 Nov 2020 21:53:46 |
| 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 'added' (Site from Safety). | Cindy Lubbers (b) (4) | 06 Nov 2020 21:50:57 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'n/a' (Site from Safety). | Cindy Lubbers (b) (4) | 06 Nov 2020 21:50:41 |
| User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety). | (b) (4), (b) (6) | 06 Nov 2020 16:56:21 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Narrative](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| 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) | 06 Nov 2020 16:56:02 |
| 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) | 06 Nov 2020 16:55:50 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 06 Nov 2020 16:55:33 |
| User entered 'Unrelated to study. Due to 5th metatarsal break that was not healing.' | Cindy Lubbers (b) (4) | 27 Oct 2020 17:49:49 |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 27 Oct 2020 17:49:49 |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 27 Oct 2020 17:49:49 |

US3532281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 27 Oct 2020 17:49:49 |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| | | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 14:14:54 |
| User closed query 'source = "Post Surgical Pain Left Ankle" please verify' (Site from CRA). | (b) (4), (b) (6) | 09 Apr 2021 14:14:50 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Post procedural pain - version MedDRA\\23.0. | Coder Import (b) (4) | 16 Mar 2021 00:51:47 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 16 Mar 2021 00:51:47 |
| Data point term sent to Coder | System | 05 Mar 2021 18:03:35 |
| Query 'source = "Post Surgical Pain Left Ankle" please verify' answered with 'CORRECTED' (Site from CRA). | Cindy Lubbers (b) (4) | 05 Mar 2021 18:03:12 |
| Coding entries removed. | Cindy Lubbers (b) (4) | 05 Mar 2021 18:03:05 |
| User entered 'POST-SURGICAL PAIN LEFT ANKLE' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 05 Mar 2021 18:03:05 |
| User opened query 'source = "Post Surgical Pain Left Ankle" please verify' (Site from CRA). | (b) (4), (b) (6) | 04 Mar 2021 21:24:13 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Postoperative pain - version MedDRA\\23.0. | Coder Import (b) (4) | 10 Nov 2020 20:04:39 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 10 Nov 2020 20:04:39 |
| Data point term sent to Coder | System | 10 Nov 2020 20:04:04 |
| User entered 'Post-surgical pain' | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:23:44 |
| | | |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:23:24 |
| | | |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:23:23 |
| | | |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 14:15:19 |
| | | |
| User closed query 'source = 23Oct2020, please verify (Site from CRA). | (b) (4), (b) (6) | 09 Apr 2021 14:15:06 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| Query 'source = 23Oct2020, please verify' answered with 'CORRECTED' (Site from CRA). | Cindy Lubbers (b) (4) | 05 Mar 2021 18:10:02 |
| | (b) (4) | |
| User entered '23 Oct 2020' reason for change: Per Query Resolution | Cindy Lubbers (b) (4) | 05 Mar 2021 18:09:39 |
| | (b) (4) | |
| User opened query 'source = 23Oct2020, please verify' (Site from CRA). | (b) (4), (b) (6) | 04 Mar 2021 21:23:18 |
| | | |
| User entered '26 Oct 2020' | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:23:20 |
| | | |
| User entered empty. | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User entered empty. | System | 10 Nov 2020 20:03:55 |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 14:16:15 |
| | | |
| User closed query 'please verify that event is continuing' (Site from CRA). | (b) (4), (b) (6) | 09 Apr 2021 14:16:13 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| Query 'please verify that event is continuing' answered with 'DONE' (Site from CRA). | Cindy Lubbers (b) (4) | 05 Mar 2021 18:12:46 |
| | (b) (4) | |
| User entered 'No (N)' reason for change: New Information | Cindy Lubbers (b) (4) | 05 Mar 2021 18:10:40 |
| | (b) (4) | |
| User opened query 'please verify that event is continuing' (Site from CRA). | (b) (4), (b) (6) | 04 Mar 2021 21:21:39 |
| | | |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User closed query 'please verify if confirmed by source (AE Log)' (Site from CRA). | (b) (4), (b) (6) | 12 Apr 2021 15:58:56 |
| Query 'please verify if confirmed by source (AE Log)' answered with 'Confirmed' (Site from CRA). | Cindy Lubbers (b) (4) | 09 Apr 2021 20:02:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Apr 2021 14:21:32 |
| | | |
| User opened query 'please verify if confirmed by source (AE Log)' (Site from CRA). | (b) (4), (b) (6) | 09 Apr 2021 14:17:58 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 05 Mar 2021 18:12:50 |
| User entered '03 Nov 2020' reason for change: New Information | Cindy Lubbers (b) (4) | 05 Mar 2021 18:12:50 |
| | (b) (4) | |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 05 Mar 2021 18:12:33 |
| User closed query 'End date is prior to Start date. Please correct.' (Site from System). | System | 05 Mar 2021 18:12:33 |
| User entered 'UN Nov 2020' (non-conformant). | Cindy Lubbers (b) (4) | 05 Mar 2021 18:12:33 |
| | (b) (4) | |
| User opened query 'End date is prior to Start date. Please correct.' (Site from System). | System | 05 Mar 2021 18:12:11 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 05 Mar 2021 18:12:11 |
| User entered '03 Sep 2020' reason for change: New Information | Cindy Lubbers (b) (4) | 05 Mar 2021 18:12:11 |
| | (b) (4) | |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 05 Mar 2021 18:11:45 |
| User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). | System | 05 Mar 2021 18:11:45 |
| Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System). | System | 05 Mar 2021 18:11:45 |
| User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System). | System | 05 Mar 2021 18:11:45 |
| DataPoint Un-verified. | Cindy Lubbers (b) (4) | 05 Mar 2021 18:11:45 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User entered 'UN Sep 2020' (non-conformant). | Cindy Lubbers (b) (4) | 05 Mar 2021 18:11:45 |
| User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System). | (b) (4) | 05 Mar 2021 18:10:40 |
| User opened query 'Outcome is Recovered/Resolved, System Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). | System | 05 Mar 2021 18:10:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:24:19 |
| User entered empty. | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:24:21 |
| | | |
| User entered empty. | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User entered empty. | System | 10 Nov 2020 20:03:55 |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[Severity](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:24:24 |
| | | |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:24:27 |
| | | |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:24:28 |
| | | |
| User entered '0' | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:24:32 |
| | | |
| User entered '0' | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:24:34 |
| | | |
| User entered '0' | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:24:35 |
| | | |
| User entered empty. | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:24:38 |
| | | |
| User entered empty. | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:24:41 |
| | | |
| User entered empty. | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:24:42 |
| | | |
| User entered empty. | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:24:44 |
| | | |
| User entered '0' | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:24:45 |
| | | |
| User entered '0' | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:24:49 |
| | | |
| User entered '0' | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:24:50 |
| | | |
| User closed query 'Per CDM: As Adverse event started after the First dose, Please review , reconcile and consider to update from "Not applicable " to appropriate details accordingly. ' (Site from DM). | (b) (4), (b) (6) | 26 Nov 2020 03:42:46 |
| | | |
| Query 'Per CDM: As Adverse event started after the First dose, Please review , reconcile and consider to update from "Not applicable " to appropriate details accordingly. ' answered with 'updated' (Site from DM). | Laila Hussaini (b) (4) | 24 Nov 2020 16:27:11 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | Laila Hussaini (b) (4) | 24 Nov 2020 16:27:01 |
| | (b) (4) | |
| User opened query 'Per CDM: As Adverse event started after the First dose, Please review , reconcile and consider to update from "Not applicable " to appropriate details accordingly. ' (Site from DM). | (b) (4), (b) (6) | 24 Nov 2020 04:57:36 |
| | | |
| Query 'Per CDM: As Adverse event started after the First dose please review , reconcile and update accordingly.' canceled (Site from DM). | (b) (4), (b) (6) | 24 Nov 2020 04:55:19 |
| | | |
| User opened query 'Per CDM: As Adverse event started after the First dose please review , reconcile and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 24 Nov 2020 04:54:50 |
| | | |
| User closed query 'Per CDM RQ: Thank you for the reponse, please update 'Relationship to Study Procedure' as appropriate. Thank you.' (Site from DM). | (b) (4), (b) (6) | 24 Nov 2020 04:54:50 |
| | | |
| Query 'Per CDM RQ: Thank you for the reponse, please update 'Relationship to Study Procedure' as appropriate. Thank you.' answered with 'updated' (Site from DM). | Laila Hussaini (b) (4) | 23 Nov 2020 14:01:48 |
| | (b) (4) | |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error | Laila Hussaini (b) (4) | 23 Nov 2020 14:01:43 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User opened query 'Per CDM RQ: Thank you for the reponse, please update 'Relationship to Study Procedure' as appropriate. Thank you.' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 04:48:03 |
| User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 04:48:03 |
| Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' answered with 'updated' (Site from DM). | Laila Hussaini (b) (4) (b) (4) | 19 Nov 2020 19:35:55 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | Laila Hussaini (b) (4) (b) (4) | 19 Nov 2020 19:35:45 |
| User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM). | (b) (4), (b) (6) | 18 Nov 2020 10:48:44 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Cindy Lubbers (b) (4) (b) (4) | 10 Nov 2020 20:03:55 |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:25:10 |
| | | |
| User closed query 'Per CDM: As Adverse event started after the First dose, Please review , reconcile and consider to update from "Not applicable " to appropriate details accordingly. ' (Site from DM). | (b) (4), (b) (6) | 26 Nov 2020 03:42:40 |
| | | |
| Query 'Per CDM: As Adverse event started after the First dose, Please review , reconcile and consider to update from "Not applicable " to appropriate details accordingly. ' answered with 'updated' (Site from DM). | Laila Hussaini (b) (4) | 24 Nov 2020 16:27:09 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | Laila Hussaini (b) (4) | 24 Nov 2020 16:27:01 |
| | (b) (4) | |
| User opened query 'Per CDM: As Adverse event started after the First dose, Please review , reconcile and consider to update from "Not applicable " to appropriate details accordingly. ' (Site from DM). | (b) (4), (b) (6) | 24 Nov 2020 04:57:14 |
| | | |
| User entered 'Not Applicable (NOT APPLICABLE)' | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:25:12 |
| | | |
| User entered 'Not Applicable (NOT APPLICABLE)' | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

None

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:25:15 |
| | | |
| User entered '0' | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:25:17 |
| | | |
| User entered 'I' | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:25:18 |
| | | |
| User entered '0' | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | (b) (4), (b) (6) | 12 Apr 2021 15:59:07 |
| User closed query 'please verify if confirmed by source (AE Log)' (Site from CRA). | Cindy Lubbers (b) (4) | 09 Apr 2021 20:02:54 |
| Query 'please verify if confirmed by source (AE Log)' answered with 'corrected in source' (Site from CRA). | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 14:21:40 |
| User opened query 'please verify if confirmed by source (AE Log)' (Site from CRA). | (b) (4), (b) (6) | 09 Apr 2021 14:19:38 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Un-verified. | Cindy Lubbers (b) (4) | 05 Mar 2021 18:10:40 |
| | (b) (4) | |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: | Cindy Lubbers (b) (4) | 05 Mar 2021 18:10:40 |
| New Information | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:25:20 |
| | (b) (4) | |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:25:22 |
| | | |
| User entered empty. | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[Narrative](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:25:27 |
| | | |
| User entered 'Subject suffered from pain after ankle surgery .' | Cindy Lubbers (b) (4) | 10 Nov 2020 20:03:55 |
| | (b) (4) | |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User entered '0' | System | 10 Nov 2020 20:03:55 |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| User entered '0' | System | 10 Nov 2020 20:03:55 |

US3532281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:09:37 |
| | | |
| | | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:42:32 |
| User signature succeeded. | Evan Anderson (b) (4) | 09 Apr 2021 08:28:41 |
| User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 03 Apr 2021 06:05:30 |
| Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'It is listed in the med history. Only 1 injection from 6 years ago.' (Site from DM). | Cindy Lubbers (b) (4) (b) (4) | 01 Apr 2021 21:28:30 |
| User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM). | (b) (4), (b) (6) | 23 Mar 2021 10:56:20 |
| Query 'Per CDM: Dermal Filler is YES, but no corresponding Con Med or Procedure appears to indicate a dermal filler. Please reconcile or provide clarification.' canceled (Site from DM). | (b) (4), (b) (6) | 23 Mar 2021 10:56:04 |
| User opened query 'Per CDM: Dermal Filler is YES, but no corresponding Con Med or Procedure appears to indicate a dermal filler. Please reconcile or provide clarification.' (Site from DM). | (b) (4), (b) (6) | 19 Mar 2021 18:26:57 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User closed query 'Per ETRTR: SAE "Left Ankle Replacement" indicated ConMeds and ConProcedures were performed. Please update ConMeds and ConProcedures as applicable, thanks.' (Site from CRA). | (b) (4), (b) (6) | 15 Nov 2020 21:06:35 |
| Query 'Per ETRTR: SAE "Left Ankle Replacement" indicated ConMeds and ConProcedures were performed. Please update ConMeds and ConProcedures as applicable, thanks.' answered with 'done' (Site from CRA). | Cindy Lubbers (b) (4) | 06 Nov 2020 15:26:10 |
| User opened query 'Per ETRTR: SAE "Left Ankle Replacement" indicated ConMeds and ConProcedures were performed. Please update ConMeds and ConProcedures as applicable, thanks.' (Site from CRA). | (b) (4), (b) (6) | 30 Oct 2020 19:45:06 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:39:12 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:56

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| 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: TELMISARTAN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 11 Sep 2020 13:41:34 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 11 Sep 2020 13:41:34 |
| Data point term sent to Coder | System | 11 Sep 2020 13:40:16 |
| User entered 'Telmisartan' | Cindy Lubbers (b) (4) (b) (4) | 11 Sep 2020 13:40:00 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:56

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:00 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:56

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Hypertension' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:00 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:56

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered '80' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:00 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:56

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'mg (mg)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:00 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:56

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:00 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:56

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:00 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:56

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:00 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:56

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:00 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:56

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:00 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'un UNK 2016' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:00 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:00 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:56

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:00 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:56

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:00 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:56

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:00 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:56

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Sep 2020 13:40:00 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Sep 2020 13:40:00 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Sep 2020 13:40:00 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:56

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 11 Sep 2020 13:41:35 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 11 Sep 2020 13:41:35 |
| Data point term sent to Coder | System | 11 Sep 2020 13:41:17 |
| User entered 'Spironolactone' | Cindy Lubbers (b) (4) (b) (4) | 11 Sep 2020 13:40:40 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:56

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:40 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:56

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Hypertension' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:40 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:56

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered '50' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:40 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:56

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'mg (mg)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:40 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:56

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:40 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:56

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:40 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:56

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:40 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:56

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:40 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:56

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:40 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'un UNK 2016' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:40 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:40 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:56

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:40 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:56

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:40 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:56

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:40:40 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:56

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Sep 2020 13:40:40 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Sep 2020 13:40:40 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Sep 2020 13:40:40 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:56

Name of Medication

| Audit | User | Time (GMT) |
|--|--|--|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: TADALAFIL - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 13 Oct 2020 18:21:15 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 13 Oct 2020 18:21:15 |
| Data point term sent to Coder Coding entries removed. | System Cindy Lubbers (b) (4) | 13 Oct 2020 18:20:41 13 Oct 2020 18:20:21 |
| User entered 'TADALafil' reason for change: Data Entry Error | Cindy Lubbers (b) (4) (b) (4) | 13 Oct 2020 18:20:21 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: TADALAFIL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 12 Sep 2020 08:03:42 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 12 Sep 2020 08:03:42 |
| Data point term sent to Coder User entered 'Tadalifis' | System Cindy Lubbers (b) (4) (b) (4) | 11 Sep 2020 13:42:18 11 Sep 2020 13:42:12 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:56

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:42:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:56

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Erectile dysfunction' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:42:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:56

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered '5' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:42:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:56

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'mg (mg)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:42:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:56

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:42:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:56

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:42:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:56

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:42:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:56

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:42:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:56

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:42:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'un UNK 2017' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:42:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:42:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:56

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:42:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:56

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:42:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:56

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:42:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:56

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Sep 2020 13:42:12 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Sep 2020 13:42:12 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Sep 2020 13:42:12 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:56

Name of Medication

| Audit | User | Time (GMT) |
|---|---------------------------------|--|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE CIPIONATE, PRODUCTSYNONYM: TESTOSTERONE CYPIONATE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 13 Oct 2020 18:22:22 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 13 Oct 2020 18:22:22 |
| Data point term sent to Coder Coding entries removed. | System Cindy Lubbers (b) (4) | 13 Oct 2020 18:21:41 13 Oct 2020 18:20:49 |
| User entered 'TESToSTERONE CYPIONATE' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 13 Oct 2020 18:20:49 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE CIPIONATE, PRODUCTSYNONYM: TESTOSTERONE CYPIONATE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Sep 2020 08:03:08 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Sep 2020 08:03:08 |
| Data point term sent to Coder User entered 'Testpsterone cypionate' | System Cindy Lubbers (b) (4) | 11 Sep 2020 13:44:21 11 Sep 2020 13:43:26 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:56

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:43:26 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:56

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Low testosterone' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:43:26 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:56

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered '06' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:43:26 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:56

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'mL (mL)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:43:26 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:56

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:43:26 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:56

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'every week (QS)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:43:26 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:56

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:43:26 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:56

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Intramuscular (INTRAMUSCULAR)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:43:26 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:56

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:43:26 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'un UNK 2010' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:43:26 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:43:26 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:56

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:43:26 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:56

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:43:26 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:56

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:43:26 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:56

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Sep 2020 13:43:26 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Sep 2020 13:43:26 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '803 (803)' | System | 11 Sep 2020 13:43:26 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:56

Name of Medication

| Audit | User | Time (GMT) |
|--|---------------------------------|--|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Dec 2020 21:14:53 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Dec 2020 21:14:53 |
| Data point term sent to Coder Coding entries removed. | System Cindy Lubbers (b) (4) | 11 Dec 2020 21:13:36 11 Dec 2020 21:13:07 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 13 Oct 2020 20:36:17 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 13 Oct 2020 20:36:17 |
| Data point term sent to Coder Coding entries removed. | System Cindy Lubbers (b) (4) | 13 Oct 2020 18:21:41 13 Oct 2020 18:21:18 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Sep 2020 14:14:34 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:56

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---|--|
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'Advil' | Coder Import (b) (4) (b) (4) System Cindy Lubbers (b) (4) (b) (4) | 11 Sep 2020 14:14:34 11 Sep 2020 13:44:21 11 Sep 2020 13:44:12 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:56

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:44:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:56

[Indication](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 14 Dec 2020 07:26:27 |
| Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'corrected' (Site from DM). | Cindy Lubbers (b) (4) (b) (4) | 11 Dec 2020 21:13:17 |
| User entered 'Osteoarthritis' reason for change: Data Entry Error | Cindy Lubbers (b) (4) (b) (4) | 11 Dec 2020 21:13:07 |
| User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM). | (b) (4), (b) (6) | 09 Dec 2020 20:26:41 |
| User entered 'GENERAL ACHES, PAINS' reason for change: Data Entry Error | Cindy Lubbers (b) (4) (b) (4) | 13 Oct 2020 18:21:18 |
| User entered 'General sches, pains' | Cindy Lubbers (b) (4) (b) (4) | 11 Sep 2020 13:44:12 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:56

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User closed query 'Per CDM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 29 Oct 2020 03:30:47 |
| Query 'Per CDM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'done' (Site from DM). | Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:44:16 |
| User entered '200' reason for change: Data Entry Error | Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:44:04 |
| User opened query 'Per CDM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 15 Oct 2020 11:07:22 |
| User entered '2' | Cindy Lubbers (b) (4) (b) (4) | 11 Sep 2020 13:44:12 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:56

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'mg (mg)' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 28 Oct 2020 15:44:04 |
| | (b) (4) | |
| User entered 'tablet (TABLET)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:44:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:56

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:44:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:56

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'as needed (PRN)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:44:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:56

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:44:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:56

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:44:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:56

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:44:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:44:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'I' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:44:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:56

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:44:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:56

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:44:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:56

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:44:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:56

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Sep 2020 13:44:12 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Sep 2020 13:44:12 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Sep 2020 13:44:12 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:56

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VENLAFAXINE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 11 Sep 2020 13:46:37 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 11 Sep 2020 13:46:37 |
| Data point term sent to Coder | System | 11 Sep 2020 13:45:24 |
| User entered 'Venlafaxine' | Cindy Lubbers (b) (4) (b) (4) | 11 Sep 2020 13:45:12 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:56

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:45:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:56

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Depression' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:45:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:56

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered '75' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:45:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:56

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'mg (mg)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:45:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:56

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:45:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:56

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:45:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:56

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:45:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:56

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:45:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:56

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:45:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'un UNK 2005' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:45:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered '0' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:45:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:56

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:45:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:56

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 11 Sep 2020 13:45:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:56

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 11 Sep 2020 13:45:12 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:56

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Sep 2020 13:45:12 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Sep 2020 13:45:12 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Sep 2020 13:45:12 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:56

Name of Medication

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:30 |
| User signature succeeded. | Evan Anderson (b) (4) | 16 Apr 2021 08:40:02 |
| User closed query 'please check if it should be AcetaminOphen' (Site from CRA). | (b) (4) | |
| 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. | (b) (4), (b) (6) | 09 Apr 2021 14:25:12 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 09 Apr 2021 13:17:59 |
| Data point term sent to Coder | (b) (4) | |
| Query 'please check if it should be AcetaminOphen' answered with 'corrected' (Site from CRA). | System | 09 Apr 2021 13:14:25 |
| Coding entries removed. | Cindy Lubbers (b) (4) | 09 Apr 2021 13:13:41 |
| Signature has been broken. | (b) (4) | |
| User entered 'ACETAMINoPHEN' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 09 Apr 2021 13:13:34 |
| User opened query 'please check if it should be AcetaminOphen' (Site from CRA). | (b) (4) | |
| Query 'please check if it should be AcetaminOphen' canceled (Site from CRA). | Cindy Lubbers (b) (4) | 09 Apr 2021 13:13:34 |
| User opened query 'please check if it should be AcetaminOphen ' (Site from CRA). | (b) (4) | |
| User signature succeeded. | Cindy Lubbers (b) (4) | 09 Apr 2021 13:13:34 |
| 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. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | (b) (4) | |
| Data point term sent to Coder | Coder Import (b) (4) | 26 Jan 2021 23:40:53 |
| | (b) (4) | |
| | Coder Import (b) (4) | 26 Jan 2021 23:40:53 |
| | (b) (4) | |
| | System | 26 Jan 2021 20:53:30 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:56

Name of Medication

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Coding entries removed. | Cindy Lubbers (b) (4) | 26 Jan 2021 20:53:24 |
| 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. | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 23 Dec 2020 17:59:47 |
| Data point term sent to Coder | (b) (4) | |
| Coding entries removed. | System | 23 Dec 2020 17:56:36 |
| | Cindy Lubbers (b) (4) | 23 Dec 2020 17:56:10 |
| | (b) (4) | |
| 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) | 29 Oct 2020 18:23:38 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | (b) (4) | |
| Data point term sent to Coder | Coder Import (b) (4) | 29 Oct 2020 18:23:38 |
| User entered 'acetaminophen' | (b) (4) | |
| | System | 28 Oct 2020 15:47:26 |
| | Cindy Lubbers (b) (4) | 28 Oct 2020 15:46:59 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:56

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:30 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'No (N)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:46:59 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:56

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:30 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Fever (documented in ediary post 2nd dose' reason for change: New Information | (b) (4) | 26 Jan 2021 20:53:24 |
| User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MUSCLE ACHES did not meet the AE reporting criteria.' (Site from DM). | (b) (4), (b) (6) | 30 Dec 2020 05:24:32 |
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MUSCLE ACHES did not meet the AE reporting criteria.' answered with 'done' (Site from DM). | Cindy Lubbers (b) (4) | 23 Dec 2020 17:56:17 |
| User entered 'Osteoarthritis' reason for change: New Information | (b) (4) | 23 Dec 2020 17:56:10 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:56

[Indication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MUSCLE ACHES did not meet the AE reporting criteria.' (Site from DM). | (b) (4), (b) (6) | 21 Dec 2020 13:29:45 |
| User entered 'muscle aches' | Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:46:59 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:56

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:30 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '325' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:46:59 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:56

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:30 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'mg (mg)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:46:59 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:56

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:30 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered empty. | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:46:59 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:56

[Frequency](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:30 |
| Query 'please check Frequency with source (Tylenol = ConMed #15)' canceled (Site from CRA). | (b) (4), (b) (6) | 07 Apr 2021 22:27:39 |
| User opened query 'please check Frequency with source (Tylenol = ConMed #15)' (Site from CRA). | (b) (4), (b) (6) | 07 Apr 2021 22:25:49 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'once daily (QD)' | (b) (4) | |
| | Cindy Lubbers (b) (4) | 28 Oct 2020 15:46:59 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:56

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:30 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered empty. | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:46:59 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:56

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:30 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Oral (ORAL)' | Cindy Lubbers (b) (4) | 28 Oct 2020 15:46:59 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:56

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:30 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered empty. | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:46:59 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:56

Start date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:30 |
| Query 'please check Start date with source (Tylenol = ConMed #15)' canceled (Site from CRA). | (b) (4), (b) (6) | 07 Apr 2021 22:27:43 |
| User opened query 'please check Start date with source (Tylenol = ConMed #15)' (Site from CRA). | (b) (4), (b) (6) | 07 Apr 2021 22:25:25 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '7 Oct 2020' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:46:59 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:30 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '0' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:46:59 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:56

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:30 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'No (N)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:46:59 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:56

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:30 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '8 Oct 2020' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:46:59 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:56

Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:24:09 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events in the study per protocol 8.3.4. Review and update entry as appropriate. Else, clarify.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 29 Jan 2021 05:31:23 |
| Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events in the study per protocol 8.3.4. Review and update entry as appropriate. Else, clarify.' answered with 'eDiary entry' (Site from DM). | Cindy Lubbers (b) (4) (b) (4) | 26 Jan 2021 20:53:53 |
| User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events in the study per protocol 8.3.4. Review and update entry as appropriate. Else, clarify.' (Site from DM). | (b) (4), (b) (6) | 24 Jan 2021 10:21:15 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:46:59 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:56

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:30 |
| User entered '1' | System | 28 Oct 2020 15:46:59 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:30 |
| User entered '1' | System | 28 Oct 2020 15:46:59 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:30 |
| User entered '804 (804)' | System | 28 Oct 2020 15:46:59 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:56

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|--|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:38 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 29 Oct 2020 18:27:44 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 29 Oct 2020 18:27:44 |
| Data point term sent to Coder User entered 'ibuprofen' | System Cindy Lubbers (b) (4) | 28 Oct 2020 15:49:29 28 Oct 2020 15:48:37 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:56

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:38 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'No (N)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:48:37 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:56

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:38 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'body aches' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:48:37 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:56

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:38 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '200' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:48:37 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:56

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:38 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'mg (mg)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:48:37 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:56

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:38 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered empty. | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:48:37 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:56

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:38 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'as needed (PRN)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:48:37 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:56

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:38 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered empty. | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:48:37 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:56

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:38 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Oral (ORAL)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:48:37 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:56

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:38 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered empty. | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:48:37 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:56

Start date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:38 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '7 Oct 2020' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:48:37 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:38 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '0' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:48:37 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:56

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:38 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'No (N)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:48:37 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:56

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:38 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '7 Oct 2020' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:48:37 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:56

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:38 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Yes (Y)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 28 Oct 2020 15:48:37 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:56

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:38 |
| User entered empty. | System | 28 Oct 2020 15:48:37 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:38 |
| User entered empty. | System | 28 Oct 2020 15:48:37 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:38 |
| User entered empty. | System | 28 Oct 2020 15:48:37 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:56

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:44 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:29:15 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 06 Nov 2020 15:52:21 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 06 Nov 2020 15:52:21 |
| Data point term sent to Coder | System | 06 Nov 2020 15:20:37 |
| User entered 'Oxycodone' | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:20:28 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:56

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:44 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:29:13 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:20:28 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:56

[Indication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:44 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:29:12 |
| User entered 'Pain from ankle surgery' | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:20:28 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:56

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:44 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:29:11 |
| User entered '5' | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:20:28 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:56

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:44 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:29:08 |
| User entered 'mg (mg)' | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:20:28 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:56

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:44 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:29:07 |
| User entered empty. | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:20:28 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:56

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:44 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:29:06 |
| User entered 'as needed (PRN)' | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:20:28 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:56

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:44 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:29:04 |
| User entered empty. | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:20:28 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:56

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:44 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:28:59 |
| User entered 'Oral (ORAL)' | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:20:28 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:56

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:44 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:28:58 |
| User entered empty. | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:20:28 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:56

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:44 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:28:56 |
| User entered '23 Oct 2020' | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:20:28 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:44 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:29:01 |
| User entered '0' | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:20:28 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:56

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 21:58:13 |
| User closed query 'please verify as ongoing' (Site from CRA). | (b) (4), (b) (6) | 02 Apr 2021 21:58:10 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Query 'please verify as ongoing' answered with 'corrected' (Site from CRA). | Cindy Lubbers (b) (4) | 05 Mar 2021 18:01:33 |
| User entered 'No (N)' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 05 Mar 2021 18:01:26 |
| User opened query 'please verify as ongoing' (Site from CRA). | (b) (4), (b) (6) | 04 Mar 2021 21:28:54 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 06 Nov 2020 15:20:28 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:56

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:44 |
| User signature succeeded. | Evan Anderson (b) (4) | 16 Apr 2021 08:40:02 |
| User closed query ' please check if should be Un Oct 2020 (per source)' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 09 Apr 2021 14:08:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 14:07:52 |
| Query ' please check if should be Un Oct 2020 (per source)' answered with 'Should be 29th - correct in source' (Site from CRA). | Cindy Lubbers (b) (4) (b) (4) | 09 Apr 2021 13:16:09 |
| User opened query ' please check if should be Un Oct 2020 (per source)' (Site from CRA). | (b) (4), (b) (6) | 07 Apr 2021 22:30:22 |
| User closed query 'please check if should be Un Oct 2020 (per source)' (Site from CRA). | (b) (4), (b) (6) | 07 Apr 2021 22:30:22 |
| Query 'please check if should be Un Oct 2020 (per source)' answered with 'corrected' (Site from CRA). | Cindy Lubbers (b) (4) (b) (4) | 06 Apr 2021 19:03:19 |
| User closed query 'End date is prior to start date. Please correct.' (Site from System). | System | 06 Apr 2021 19:03:10 |
| User entered '29 Oct 2020' reason for change: New Information | Cindy Lubbers (b) (4) (b) (4) | 06 Apr 2021 19:03:10 |
| User opened query 'End date is prior to start date. Please correct.' (Site from System). | System | 06 Apr 2021 18:48:28 |
| DataPoint Un-verified. | Cindy Lubbers (b) (4) (b) (4) | 06 Apr 2021 18:48:28 |
| Signature has been broken. | Cindy Lubbers (b) (4) (b) (4) | 06 Apr 2021 18:48:28 |
| User entered 'UN Oct 2020' reason for change: New Information | Cindy Lubbers (b) (4) (b) (4) | 06 Apr 2021 18:48:28 |
| User opened query 'please check if should be Un Oct 2020 (per source)' (Site from CRA). | (b) (4), (b) (6) | 02 Apr 2021 21:59:19 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 21:58:15 |
| User signature succeeded. | Evan Anderson (b) (4) (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'un Nov 2020' reason for change: New Information | Cindy Lubbers (b) (4) (b) (4) | 05 Mar 2021 18:01:26 |
| User entered empty. | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:20:28 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:56

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:44 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:29:20 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:20:28 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:56

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:44 |
| User entered empty. | System | 06 Nov 2020 15:20:28 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:44 |
| User entered empty. | System | 06 Nov 2020 15:20:28 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:44 |
| User entered empty. | System | 06 Nov 2020 15:20:28 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:56

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:51 |
| User signature succeeded. | Evan Anderson (b) (4) | 16 Apr 2021 08:40:02 |
| User closed query 'please check if it should be AcetaminOphen ' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 09 Apr 2021 14:08:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 14:07:54 |
| 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) (b) (4) | 09 Apr 2021 13:18:46 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 09 Apr 2021 13:18:46 |
| Data point term sent to Coder | System | 09 Apr 2021 13:17:29 |
| Query 'please check if it should be AcetaminOphen ' answered with 'corrected' (Site from CRA). | Cindy Lubbers (b) (4) (b) (4) | 09 Apr 2021 13:17:15 |
| DataPoint Un-verified. | Cindy Lubbers (b) (4) (b) (4) | 09 Apr 2021 13:16:33 |
| Coding entries removed. | Cindy Lubbers (b) (4) (b) (4) | 09 Apr 2021 13:16:33 |
| Signature has been broken. | Cindy Lubbers (b) (4) (b) (4) | 09 Apr 2021 13:16:33 |
| User entered 'Acetaminophen' reason for change: Data Entry Error | Cindy Lubbers (b) (4) (b) (4) | 09 Apr 2021 13:16:33 |
| User opened query 'please check if it should be AcetaminOphen ' (Site from CRA). | (b) (4), (b) (6) | 07 Apr 2021 22:17:19 |
| User closed query 'please check if Polyethylene glycol should be added for SAE treatment' (Site from CRA). | (b) (4), (b) (6) | 07 Apr 2021 22:13:15 |
| User signature succeeded. | Evan Anderson (b) (4) (b) (4) | 02 Apr 2021 18:55:04 |
| Query 'please check if Polyethylene glycol should be added for SAE treatment' answered with 'added' (Site from CRA). | Cindy Lubbers (b) (4) (b) (4) | 30 Mar 2021 21:43:47 |
| User opened query 'please check if Polyethylene glycol should be added for SAE treatment' (Site from CRA). | (b) (4), (b) (6) | 25 Mar 2021 19:27:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:29:33 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:56

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| 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) (b) (4) | 06 Nov 2020 15:44:18 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 06 Nov 2020 15:44:18 |
| Data point term sent to Coder | System | 06 Nov 2020 15:23:39 |
| User entered 'Acetaminiphen' | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:23:31 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:56

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:51 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:29:35 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:23:31 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:56

[Indication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:51 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:29:37 |
| User entered 'pain from ankle surgery' | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:23:31 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:56

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:51 |
| User closed query 'Per D/C summary dose = 975 mg, please verify' (Site from CRA). | (b) (4), (b) (6) | 07 Apr 2021 22:09:57 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:09:55 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Query 'Per D/C summary dose = 975 mg, please verify' answered with 'corrected' (Site from CRA). | (b) (4) | |
| User entered '975' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 05 Mar 2021 17:50:17 |
| User opened query 'Per D/C summary dose = 975 mg, please verify' (Site from CRA). | (b) (4) | |
| DataPoint Un-verified. | Cindy Lubbers (b) (4) | 05 Mar 2021 17:50:08 |
| | (b) (4) | |
| | (b) (4), (b) (6) | 04 Mar 2021 21:32:48 |
| | (b) (4), (b) (6) | 04 Mar 2021 21:32:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:30:04 |
| User entered '1000' | Cindy Lubbers (b) (4) | 06 Nov 2020 15:23:31 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:56

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:51 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:30:08 |
| User entered 'mg (mg)' | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:23:31 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:56

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:51 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:30:07 |
| User entered empty. | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:23:31 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:56

[Frequency](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:51 |
| User closed query 'per D/C summary q 6 hours, please verify' (Site from CRA). | (b) (4), (b) (6) | 07 Apr 2021 22:09:46 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:09:44 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Query 'per D/C summary q 6 hours, please verify' answered with 'corrected' (Site from CRA). | (b) (4) | |
| | Cindy Lubbers (b) (4) | 05 Mar 2021 17:50:24 |
| User entered 'four times daily (QID)' reason for change: Per Query Resolution | (b) (4) | |
| | Cindy Lubbers (b) (4) | 05 Mar 2021 17:50:08 |
| User opened query 'per D/C summary q 6 hours, please verify' (Site from CRA). | (b) (4), (b) (6) | 04 Mar 2021 21:33:06 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 04 Mar 2021 21:30:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 21:30:12 |
| User entered 'as needed (PRN)' | Cindy Lubbers (b) (4) | 06 Nov 2020 15:23:31 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:56

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:51 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:09:49 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered empty. | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:23:31 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:56

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:51 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:33:49 |
| User entered 'Oral (ORAL)' | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:23:31 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:56

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:51 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:33:45 |
| User entered empty. | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:23:31 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:56

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:51 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:33:34 |
| User entered '23 Oct 2020' | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:23:31 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:51 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:33:44 |
| User entered '0' | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:23:31 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:56

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:51 |
| User closed query 'per D/C summary , 10 days only, please verify' (Site from CRA). | (b) (4), (b) (6) | 07 Apr 2021 22:07:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:07:57 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Query 'per D/C summary , 10 days only, please verify' answered with 'corrected' (Site from CRA). | (b) (4) | |
| | Cindy Lubbers (b) (4) | 05 Mar 2021 17:50:44 |
| User entered 'No (N)' reason for change: Per Query Resolution | (b) (4) | |
| | Cindy Lubbers (b) (4) | 05 Mar 2021 17:50:08 |
| User opened query 'per D/C summary , 10 days only, please verify' (Site from CRA). | (b) (4), (b) (6) | 04 Mar 2021 21:33:26 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Cindy Lubbers (b) (4) | 06 Nov 2020 15:23:31 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:56

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:51 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:07:28 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System). | (b) (4) | 05 Mar 2021 17:50:47 |
| User entered '03 Nov 2020' reason for change: Per Query Resolution | Cindy Lubbers (b) (4) | 05 Mar 2021 17:50:47 |
| User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System). | System | 05 Mar 2021 17:50:08 |
| User entered empty. | Cindy Lubbers (b) (4) | 06 Nov 2020 15:23:31 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:56

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:51 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:33:29 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:23:31 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:56

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:51 |
| User entered '4' | System | 05 Mar 2021 17:50:08 |
| User entered empty. | System | 06 Nov 2020 15:23:31 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:51 |
| User entered '1' | System | 05 Mar 2021 17:50:08 |
| User entered empty. | System | 06 Nov 2020 15:23:31 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:43:51 |
| User entered '804 (804)' | System | 05 Mar 2021 17:50:08 |
| User entered empty. | System | 06 Nov 2020 15:23:31 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:56

Name of Medication

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 04 Mar 2021 21:34:02 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 06 Nov 2020 15:45:19 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 06 Nov 2020 15:45:19 |
| | (b) (4) | |
| Data point term sent to Coder | System | 06 Nov 2020 15:24:41 |
| User entered 'Aspirin' | Cindy Lubbers (b) (4) | 06 Nov 2020 15:24:20 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:56

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:34:03 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:24:20 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:56

[Indication](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:34:05 |
| User entered 'DVT prevention after ankle surgery' | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:24:20 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:56

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 04 Mar 2021 21:34:07 |
| User entered '325' | Cindy Lubbers (b) (4) | 06 Nov 2020 15:24:20 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:56

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 04 Mar 2021 21:34:10 |
| User entered 'mg (mg)' | Cindy Lubbers (b) (4) | 06 Nov 2020 15:24:20 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:56

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 04 Mar 2021 21:34:13 |
| User entered empty. | Cindy Lubbers (b) (4) | 06 Nov 2020 15:24:20 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:56

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 04 Mar 2021 21:34:15 |
| User entered 'once daily (QD)' | Cindy Lubbers (b) (4) | 06 Nov 2020 15:24:20 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:56

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:34:17 |
| User entered empty. | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:24:20 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:56

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:34:18 |
| User entered 'Oral (ORAL)' | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:24:20 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:56

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 04 Mar 2021 21:34:21 |
| User entered empty. | Cindy Lubbers (b) (4) | 06 Nov 2020 15:24:20 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:56

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 04 Mar 2021 21:34:23 |
| User entered '23 Oct 2020' | Cindy Lubbers (b) (4) | 06 Nov 2020 15:24:20 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 04 Mar 2021 21:34:26 |
| User entered '0' | Cindy Lubbers (b) (4) | 06 Nov 2020 15:24:20 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:56

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:34:28 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:24:20 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:56

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:34:29 |
| User entered empty. | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:24:20 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:56

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 21:34:31 |
| User entered 'No (N)' | Cindy Lubbers (b) (4) (b) (4) | 06 Nov 2020 15:24:20 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:56

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Nov 2020 15:24:20 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Nov 2020 15:24:20 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 06 Nov 2020 15:24:20 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:56

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:44:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 14:05:51 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL, PRODUCTSYNONYM: POLYETHYLENE GLYCOL [MACROGOL] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 07 Apr 2021 09:40:32 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 07 Apr 2021 09:40:32 |
| Data point term sent to Coder | System | 06 Apr 2021 18:56:50 |
| Coding entries removed. | Cindy Lubbers (b) (4) (b) (4) | 06 Apr 2021 18:55:54 |
| User signature succeeded. | Evan Anderson (b) (4) (b) (4) | 02 Apr 2021 18:55:04 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL, PRODUCTSYNONYM: POLYETHYLENE GLYCOL [MACROGOL] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 31 Mar 2021 07:30:28 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 31 Mar 2021 07:30:28 |
| Data point term sent to Coder | System | 30 Mar 2021 21:46:11 |
| User entered 'Polyethylene glycol' | Cindy Lubbers (b) (4) (b) (4) | 30 Mar 2021 21:45:56 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:56

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:44:00 |
| User signature succeeded. | Evan Anderson (b) (4) | 16 Apr 2021 08:40:02 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Apr 2021 14:05:51 |
| Signature has been broken. | Cindy Lubbers (b) (4) | 06 Apr 2021 18:55:54 |
| User entered 'Yes (Y)' reason for change: Per Query Resolution | (b) (4) Cindy Lubbers (b) (4) | 06 Apr 2021 18:55:54 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'No (N)' | (b) (4) Cindy Lubbers (b) (4) | 30 Mar 2021 21:45:56 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:56

[Indication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:44:00 |
| User signature succeeded. | Evan Anderson (b) (4) | 16 Apr 2021 08:40:02 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Apr 2021 14:05:51 |
| User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match.. Update eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 08 Apr 2021 02:39:10 |
| Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match.. Update eCRF as appropriate. ' answered with 'corrected' (Site from DM). | Cindy Lubbers (b) (4) (b) (4) | 06 Apr 2021 18:56:03 |
| Signature has been broken. | Cindy Lubbers (b) (4) (b) (4) | 06 Apr 2021 18:55:54 |
| User entered 'bowel management -prevention of constipation caused by pain medication' reason for change: Per Query Resolution | Cindy Lubbers (b) (4) (b) (4) | 06 Apr 2021 18:55:54 |
| User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match.. Update eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 06 Apr 2021 11:25:17 |
| User signature succeeded. | Evan Anderson (b) (4) (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Bowel management' | Cindy Lubbers (b) (4) (b) (4) | 30 Mar 2021 21:45:56 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:56

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:44:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 14:05:51 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '17' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 30 Mar 2021 21:45:56 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:56

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:44:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 14:05:51 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'g (g)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 30 Mar 2021 21:45:56 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:56

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:44:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 14:05:51 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered empty. | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 30 Mar 2021 21:45:56 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:56

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:44:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 14:05:51 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'once daily (QD)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 30 Mar 2021 21:45:56 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:56

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:44:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 14:05:51 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered empty. | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 30 Mar 2021 21:45:56 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:56

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:44:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 14:05:51 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Oral (ORAL)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 30 Mar 2021 21:45:56 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:56

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:44:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 14:05:51 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered empty. | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 30 Mar 2021 21:45:56 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:56

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:44:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 14:05:51 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '25 Oct 2020' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 30 Mar 2021 21:45:56 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:44:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 14:05:51 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '0' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 30 Mar 2021 21:45:56 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:56

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:44:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 14:05:51 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'No (N)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 30 Mar 2021 21:45:56 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:56

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:44:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 14:05:51 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '28 Oct 2020' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 30 Mar 2021 21:45:56 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:56

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:44:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Apr 2021 14:05:51 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'No (N)' | (b) (4) Cindy Lubbers (b) (4) (b) (4) | 30 Mar 2021 21:45:56 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:56

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:44:00 |
| User entered '1' | System | 30 Mar 2021 21:45:56 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:44:00 |
| User entered '1' | System | 30 Mar 2021 21:45:56 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:44:00 |
| User entered '804 (804)' | System | 30 Mar 2021 21:45:56 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:56

Name of Medication

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 16 Apr 2021 08:40:02 |
| User closed query 'please check with source if should be ADDERALL XR' (Site from CRA). | (b) (4) | |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE, PRODUCTSYNONYM: ADDERALL - version WHODrug-Global-B3\\202003. | (b) (4), (b) (6) | 12 Apr 2021 15:49:42 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE, PRODUCTSYNONYM: ADDERALL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 09 Apr 2021 19:55:53 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | (b) (4) | |
| Query 'please check with source if should be ADDERALL XR' answered with 'corrected' (Site from CRA). | Cindy Lubbers (b) (4) | 09 Apr 2021 19:55:34 |
| Data point term sent to Coder | (b) (4) | |
| Coding entries removed. | System | 09 Apr 2021 19:55:24 |
| | Cindy Lubbers (b) (4) | 09 Apr 2021 19:55:17 |
| | (b) (4) | |
| Signature has been broken. | Cindy Lubbers (b) (4) | 09 Apr 2021 19:55:17 |
| | (b) (4) | |
| User entered 'ADDERALL Xr' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 09 Apr 2021 19:55:17 |
| User opened query 'please check with source if should be ADDERALL XR' (Site from CRA). | (b) (4), (b) (6) | 09 Apr 2021 14:24:45 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE, PRODUCTSYNONYM: ADDERALL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 31 Mar 2021 21:14:04 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:56

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User coded data point as Term Coded data point by | Coder Import (b) (4) | 31 Mar 2021 21:14:04 |
| User: Coder System - version | (b) (4) | |
| WHODrug-Global-B3\\202003. | | |
| Data point term sent to Coder | System | 31 Mar 2021 21:12:52 |
| User entered 'Adderall XL' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:12:13 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:56

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:12:13 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:56

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'ADHD' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:12:13 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:56

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 16 Apr 2021 08:40:02 |
| User closed query 'please check with source if dose to be changed to 12.5 mg' (Site from CRA). | (b) (4) | |
| Query 'please check with source if dose to be changed to 12.5 mg' answered with 'corrected' (Site from CRA). | (b) (4), (b) (6) | 12 Apr 2021 15:49:45 |
| Signature has been broken. | Cindy Lubbers (b) (4) | 09 Apr 2021 19:55:57 |
| User entered '12.5' reason for change: Per Query Resolution | (b) (4) | |
| User opened query 'please check with source if dose to be changed to 12.5 mg' (Site from CRA). | Cindy Lubbers (b) (4) | 09 Apr 2021 19:55:17 |
| User signature succeeded. | (b) (4) | |
| User entered '25' | (b) (4), (b) (6) | 09 Apr 2021 14:24:04 |
| | | |
| | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| | Cindy Lubbers (b) (4) | 31 Mar 2021 21:12:13 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:56

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'mg (mg)' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:12:13 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:56

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 31 Mar 2021 21:12:13 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:56

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:12:13 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:56

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 31 Mar 2021 21:12:13 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:56

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:12:13 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:56

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 31 Mar 2021 21:12:13 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'un UNK 2012' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:12:13 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered '0' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:12:13 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:56

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:12:13 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:56

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 31 Mar 2021 21:12:13 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:56

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:12:13 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:56

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 31 Mar 2021 21:12:13 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 31 Mar 2021 21:12:13 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 31 Mar 2021 21:12:13 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:56

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 31 Mar 2021 21:17:05 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 31 Mar 2021 21:17:05 |
| Data point term sent to Coder | System | 31 Mar 2021 21:15:54 |
| User entered 'Flonase' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:15:19 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:56

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:15:19 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:56

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Seasonal allergies' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:15:19 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:56

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered '2' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:15:19 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:56

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Other (OTHER)' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:15:19 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:56

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'sprays' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:15:19 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:56

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'as needed (PRN)' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:15:19 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:56

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 31 Mar 2021 21:15:19 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:56

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 31 Mar 2021 21:15:27 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 31 Mar 2021 21:15:27 |
| User entered 'Nasal (NASAL)' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 31 Mar 2021 21:15:27 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 31 Mar 2021 21:15:19 |
| User entered empty. | Cindy Lubbers (b) (4) | 31 Mar 2021 21:15:19 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:56

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 31 Mar 2021 21:15:19 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'un UNK 2019' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:15:19 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered '0' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:15:19 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:56

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:15:19 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:56

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 31 Mar 2021 21:15:19 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:56

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:15:19 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:56

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Mar 2021 21:15:19 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Mar 2021 21:15:19 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Mar 2021 21:15:19 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:56

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 06 Apr 2021 13:17:53 |
| 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 Apr 2021 13:17:53 |
| User signature succeeded. | Evan Anderson (b) (4) (b) (4) | 02 Apr 2021 18:55:04 |
| Data point term sent to Coder | System | 31 Mar 2021 21:17:55 |
| User entered 'Multivitamin- Men's 50' | Cindy Lubbers (b) (4) (b) (4) | 31 Mar 2021 21:16:59 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:56

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:16:59 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:56

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'General health' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:16:59 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:56

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered '1' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:16:59 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:56

[Dose unit](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'tablet (TABLET)' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:16:59 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:56

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 31 Mar 2021 21:16:59 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:56

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:16:59 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:56

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 31 Mar 2021 21:16:59 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:56

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:16:59 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:56

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 31 Mar 2021 21:16:59 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:56

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'un UNK 2019' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:16:59 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:56

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered '0' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:16:59 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:56

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:16:59 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:56

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered empty. | Cindy Lubbers (b) (4) | 31 Mar 2021 21:16:59 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:56

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| | (b) (4) | |
| User entered 'No (N)' | Cindy Lubbers (b) (4) | 31 Mar 2021 21:16:59 |
| | (b) (4) | |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:56

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 31 Mar 2021 21:16:59 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 31 Mar 2021 21:16:59 |

US3532281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:56

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 31 Mar 2021 21:16:59 |

US3532281

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:09:56

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:42:32 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4) | 02 Nov 2020 15:34:16 |

US3532281

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:09:56

[Procedure/Surgery date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Mar 2021 19:24:08 |
| User entered '23 Oct 2020' | Cindy Lubbers (b) (4) (b) (4) | 02 Nov 2020 15:35:24 |

US3532281

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:09:56

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Mar 2021 19:24:09 |
| User closed query 'D/C summary = Left Total Ankle Arthroplasty, please verify' (Site from CRA). | (b) (4), (b) (6) | 25 Mar 2021 18:59:28 |
| Query 'D/C summary = Left Total Ankle Arthroplasty, please verify' answered with 'Corrected' (Site from CRA). | Cindy Lubbers (b) (4) | 05 Mar 2021 15:01:29 |
| User entered 'LEFT Total Ankle Arthroplasty' reason for change: Data Entry Error | (b) (4) | 05 Mar 2021 15:01:21 |
| User opened query 'D/C summary = Left Total Ankle Arthroplasty, please verify' (Site from CRA). | (b) (4), (b) (6) | 04 Mar 2021 20:56:32 |
| User entered 'Left ankle replacement' | Cindy Lubbers (b) (4) | 02 Nov 2020 15:35:24 |
| | (b) (4) | |

US3532281

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:09:56

[Indication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 21:56:42 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User closed query 'Per DM CLR: Indication = OTHER, however, please confirm if the procedure was done for a medical condition. If yes, please record the condition in the appropriate eCRF page (i.e. AE/MedHistory) and update indication as applicable. Reconcile as appropriate, otherwise clarify. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 01 Apr 2021 10:03:54 |
| Query 'Per DM CLR: Indication = OTHER, however, please confirm if the procedure was done for a medical condition. If yes, please record the condition in the appropriate eCRF page (i.e. AE/MedHistory) and update indication as applicable. Reconcile as appropriate, otherwise clarify. ' answered with 'Done for worsening osteoarthritis in left ankle' (Site from DM). | Cindy Lubbers (b) (4) (b) (4) | 31 Mar 2021 13:30:11 |
| DataPoint Un-verified. | Cindy Lubbers (b) (4) (b) (4) | 31 Mar 2021 13:28:57 |
| User entered 'Medical History (MH)' reason for change: Per Query Resolution | Cindy Lubbers (b) (4) (b) (4) | 31 Mar 2021 13:28:57 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Mar 2021 19:24:10 |
| User opened query 'Per DM CLR: Indication = OTHER, however, please confirm if the procedure was done for a medical condition. If yes, please record the condition in the appropriate eCRF page (i.e. AE/MedHistory) and update indication as applicable. Reconcile as appropriate, otherwise clarify. ' (Site from DM). | (b) (4), (b) (6) | 22 Mar 2021 08:32:54 |
| User closed query 'Per DM CLR: Indication = OTHER, however, please confirm if the indication could be recorded as one of the available choice (i.e. MedHistory) as there is a recorded conditions in the MedHistory eCRF that possibly matches this procedure. Reconcile and update as appropriate, otherwise provide clarification.' (Site from DM). | (b) (4), (b) (6) | 09 Dec 2020 13:34:18 |

US3532281

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:09:56

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Query 'Per DM CLR: Indication = OTHER, however, please confirm if the indication could be recorded as one of the available choice (i.e. MedHistory) as there is a recorded conditions in the MedHistory eCRF that possibly matches this procedure. Reconcile and update as appropriate, otherwise provide clarification.' answered with 'DONE' (Site from DM). | Cindy Lubbers (b) (4) | 07 Dec 2020 20:41:10 |
| User opened query 'Per DM CLR: Indication = OTHER, however, please confirm if the indication could be recorded as one of the available choice (i.e. MedHistory) as there is a recorded conditions in the MedHistory eCRF that possibly matches this procedure. Reconcile and update as appropriate, otherwise provide clarification.' (Site from DM). | (b) (4), (b) (6) | 02 Dec 2020 15:30:47 |
| User entered 'Other (OTHER)' | Cindy Lubbers (b) (4) | 02 Nov 2020 15:35:24 |

US3532281

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:09:56

If indication is Other, specify

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 21:56:44 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| DataPoint Un-verified. | Cindy Lubbers (b) (4) | 31 Mar 2021 13:28:57 |
| User entered empty; reason for change Data Entry Error | Cindy Lubbers (b) (4) | 31 Mar 2021 13:28:57 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Mar 2021 19:24:13 |
| User entered 'SCHEDULED SURGERY FOR FIFTH MEDITARSAL BREAK' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 07 Dec 2020 20:41:05 |
| User entered 'Scheduled SURGERY' reason for change: Data Entry Error | Cindy Lubbers (b) (4) | 02 Nov 2020 15:35:43 |
| User entered 'Planned surgery' | Cindy Lubbers (b) (4) | 02 Nov 2020 15:35:24 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'USA-US077-2020-MRNA-1273-P301000006' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Yes (Y)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Yes (Y)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Evan' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Anderson' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-------------------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered '2015 Uppergate Drive' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Atlanta' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'GA' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered '30323' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 19:05:31 |
| User entered 'US' | System | 28 Oct 2020 17:09:18 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '10' | System | 09 Apr 2021 18:44:54 |
| User entered '9' | System | 01 Apr 2021 14:23:38 |
| User entered '8' | System | 08 Mar 2021 17:04:59 |
| User entered '7' | System | 08 Feb 2021 14:46:50 |
| User entered '6' | System | 04 Feb 2021 19:19:33 |
| User entered '5' | System | 06 Jan 2021 16:45:15 |
| User entered '4' | System | 01 Dec 2020 15:30:04 |
| User entered '3' | System | 18 Nov 2020 16:24:16 |
| User entered '2' | System | 09 Nov 2020 19:05:39 |
| User entered '1' | System | 28 Oct 2020 17:09:18 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'USA-US077-2020-MRNA-1273-P301000006' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Yes (Y)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Yes (Y)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Evan' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Anderson' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-------------------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered '2015 Uppergate Drive' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Atlanta' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'GA' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered '30323' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 19:05:31 |
| User entered 'US' | System | 28 Oct 2020 17:09:18 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '10' | System | 09 Apr 2021 18:44:54 |
| User entered '9' | System | 01 Apr 2021 14:23:38 |
| User entered '8' | System | 08 Mar 2021 17:04:59 |
| User entered '7' | System | 08 Feb 2021 14:46:50 |
| User entered '6' | System | 04 Feb 2021 19:19:33 |
| User entered '5' | System | 06 Jan 2021 16:45:15 |
| User entered '4' | System | 01 Dec 2020 15:30:04 |
| User entered '3' | System | 18 Nov 2020 16:24:16 |
| User entered '2' | System | 09 Nov 2020 19:05:39 |
| User entered '1' | System | 28 Oct 2020 17:09:18 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:09:56

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '28/Oct/2020 13:09' | (b) (4) System | 28 Oct 2020 17:09:18 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:09:56

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) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 19:05:31 |
| User entered 'I' | (b) (4), (b) (6) | 28 Oct 2020 17:09:18 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'USA-US077-2020-MRNA-1273-P301000006' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Yes (Y)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Yes (Y)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Evan' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Anderson' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-------------------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered '2015 Uppergate Drive' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Atlanta' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'GA' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered '30323' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 19:05:31 |
| User entered 'US' | System | 28 Oct 2020 17:09:18 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '10' | System | 09 Apr 2021 18:44:54 |
| User entered '9' | System | 01 Apr 2021 14:23:38 |
| User entered '8' | System | 08 Mar 2021 17:04:59 |
| User entered '7' | System | 08 Feb 2021 14:46:50 |
| User entered '6' | System | 04 Feb 2021 19:19:33 |
| User entered '5' | System | 06 Jan 2021 16:45:15 |
| User entered '4' | System | 01 Dec 2020 15:30:04 |
| User entered '3' | System | 18 Nov 2020 16:24:16 |
| User entered '2' | System | 09 Nov 2020 19:05:39 |
| User entered '1' | System | 28 Oct 2020 17:09:18 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:09:56

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '09/Nov/2020 19:05' | (b) (4) System | 09 Nov 2020 19:05:39 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:09:56

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) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 16:24:06 |
| User entered 'I' | (b) (4), (b) (6) | 09 Nov 2020 19:05:39 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'USA-US077-2020-MRNA-1273-P301000006' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Yes (Y)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Yes (Y)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Evan' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Anderson' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-------------------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered '2015 Uppergate Drive' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Atlanta' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'GA' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered '30323' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 19:05:31 |
| User entered 'US' | System | 28 Oct 2020 17:09:18 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '10' | System | 09 Apr 2021 18:44:54 |
| User entered '9' | System | 01 Apr 2021 14:23:38 |
| User entered '8' | System | 08 Mar 2021 17:04:59 |
| User entered '7' | System | 08 Feb 2021 14:46:50 |
| User entered '6' | System | 04 Feb 2021 19:19:33 |
| User entered '5' | System | 06 Jan 2021 16:45:15 |
| User entered '4' | System | 01 Dec 2020 15:30:04 |
| User entered '3' | System | 18 Nov 2020 16:24:16 |
| User entered '2' | System | 09 Nov 2020 19:05:39 |
| User entered '1' | System | 28 Oct 2020 17:09:18 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:09:56

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '18/Nov/2020 16:24' | (b) (4) System | 18 Nov 2020 16:24:16 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:09:56

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) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 01 Dec 2020 15:29:53 |
| User entered 'I' | (b) (4), (b) (6) | 18 Nov 2020 16:24:16 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'USA-US077-2020-MRNA-1273-P301000006' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Yes (Y)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Yes (Y)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Evan' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Anderson' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-------------------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered '2015 Uppergate Drive' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Atlanta' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'GA' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered '30323' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 19:05:31 |
| User entered 'US' | System | 28 Oct 2020 17:09:18 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '10' | System | 09 Apr 2021 18:44:54 |
| User entered '9' | System | 01 Apr 2021 14:23:38 |
| User entered '8' | System | 08 Mar 2021 17:04:59 |
| User entered '7' | System | 08 Feb 2021 14:46:50 |
| User entered '6' | System | 04 Feb 2021 19:19:33 |
| User entered '5' | System | 06 Jan 2021 16:45:15 |
| User entered '4' | System | 01 Dec 2020 15:30:04 |
| User entered '3' | System | 18 Nov 2020 16:24:16 |
| User entered '2' | System | 09 Nov 2020 19:05:39 |
| User entered '1' | System | 28 Oct 2020 17:09:18 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:09:56

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '01/Dec/2020 10:30' | (b) (4) System | 01 Dec 2020 15:30:04 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:09:56

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) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 06 Jan 2021 16:45:07 |
| User entered 'I' | (b) (4), (b) (6) | 01 Dec 2020 15:30:04 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'USA-US077-2020-MRNA-1273-P301000006' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Yes (Y)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Yes (Y)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Evan' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Anderson' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-------------------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered '2015 Uppergate Drive' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Atlanta' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'GA' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered '30323' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 19:05:31 |
| User entered 'US' | System | 28 Oct 2020 17:09:18 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '10' | System | 09 Apr 2021 18:44:54 |
| User entered '9' | System | 01 Apr 2021 14:23:38 |
| User entered '8' | System | 08 Mar 2021 17:04:59 |
| User entered '7' | System | 08 Feb 2021 14:46:50 |
| User entered '6' | System | 04 Feb 2021 19:19:33 |
| User entered '5' | System | 06 Jan 2021 16:45:15 |
| User entered '4' | System | 01 Dec 2020 15:30:04 |
| User entered '3' | System | 18 Nov 2020 16:24:16 |
| User entered '2' | System | 09 Nov 2020 19:05:39 |
| User entered '1' | System | 28 Oct 2020 17:09:18 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:09:56

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '06/Jan/2021 16:45' | (b) (4) System | 06 Jan 2021 16:45:15 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:09:56

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) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Feb 2021 19:19:14 |
| User entered 'I' | (b) (4), (b) (6) | 06 Jan 2021 16:45:15 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'USA-US077-2020-MRNA-1273-P301000006' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Yes (Y)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Yes (Y)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Evan' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Anderson' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-------------------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered '2015 Uppergate Drive' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Atlanta' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'GA' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered '30323' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 19:05:31 |
| User entered 'US' | System | 28 Oct 2020 17:09:18 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '10' | System | 09 Apr 2021 18:44:54 |
| User entered '9' | System | 01 Apr 2021 14:23:38 |
| User entered '8' | System | 08 Mar 2021 17:04:59 |
| User entered '7' | System | 08 Feb 2021 14:46:50 |
| User entered '6' | System | 04 Feb 2021 19:19:33 |
| User entered '5' | System | 06 Jan 2021 16:45:15 |
| User entered '4' | System | 01 Dec 2020 15:30:04 |
| User entered '3' | System | 18 Nov 2020 16:24:16 |
| User entered '2' | System | 09 Nov 2020 19:05:39 |
| User entered '1' | System | 28 Oct 2020 17:09:18 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:09:56

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '04/Feb/2021 14:19' | (b) (4) System | 04 Feb 2021 19:19:33 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:09:56

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) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 04 Feb 2021 19:19:53 |
| User entered 'I' | (b) (4), (b) (6) | 04 Feb 2021 19:19:33 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'USA-US077-2020-MRNA-1273-P301000006' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Yes (Y)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Yes (Y)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Evan' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Anderson' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-------------------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered '2015 Uppergate Drive' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Atlanta' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'GA' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered '30323' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 19:05:31 |
| User entered 'US' | System | 28 Oct 2020 17:09:18 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '10' | System | 09 Apr 2021 18:44:54 |
| User entered '9' | System | 01 Apr 2021 14:23:38 |
| User entered '8' | System | 08 Mar 2021 17:04:59 |
| User entered '7' | System | 08 Feb 2021 14:46:50 |
| User entered '6' | System | 04 Feb 2021 19:19:33 |
| User entered '5' | System | 06 Jan 2021 16:45:15 |
| User entered '4' | System | 01 Dec 2020 15:30:04 |
| User entered '3' | System | 18 Nov 2020 16:24:16 |
| User entered '2' | System | 09 Nov 2020 19:05:39 |
| User entered '1' | System | 28 Oct 2020 17:09:18 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:09:56

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '08/Feb/2021 14:46' | (b) (4) System | 08 Feb 2021 14:46:50 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:09:56

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) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 08 Mar 2021 17:04:47 |
| User entered 'I' | (b) (4), (b) (6) | 08 Feb 2021 14:46:50 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'USA-US077-2020-MRNA-1273-P301000006' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Yes (Y)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Yes (Y)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Evan' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Anderson' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-------------------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered '2015 Uppergate Drive' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Atlanta' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'GA' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered '30323' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 19:05:31 |
| User entered 'US' | System | 28 Oct 2020 17:09:18 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '10' | System | 09 Apr 2021 18:44:54 |
| User entered '9' | System | 01 Apr 2021 14:23:38 |
| User entered '8' | System | 08 Mar 2021 17:04:59 |
| User entered '7' | System | 08 Feb 2021 14:46:50 |
| User entered '6' | System | 04 Feb 2021 19:19:33 |
| User entered '5' | System | 06 Jan 2021 16:45:15 |
| User entered '4' | System | 01 Dec 2020 15:30:04 |
| User entered '3' | System | 18 Nov 2020 16:24:16 |
| User entered '2' | System | 09 Nov 2020 19:05:39 |
| User entered '1' | System | 28 Oct 2020 17:09:18 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 08:09:56

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '08/Mar/2021 12:04' | (b) (4) System | 08 Mar 2021 17:04:59 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 08:09:56

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) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 01 Apr 2021 14:23:22 |
| User entered 'I' | (b) (4), (b) (6) | 08 Mar 2021 17:04:59 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'USA-US077-2020-MRNA-1273-P301000006' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Yes (Y)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Yes (Y)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Evan' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Anderson' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-------------------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered '2015 Uppergate Drive' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Atlanta' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'GA' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered '30323' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 19:05:31 |
| User entered 'US' | System | 28 Oct 2020 17:09:18 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '10' | System | 09 Apr 2021 18:44:54 |
| User entered '9' | System | 01 Apr 2021 14:23:38 |
| User entered '8' | System | 08 Mar 2021 17:04:59 |
| User entered '7' | System | 08 Feb 2021 14:46:50 |
| User entered '6' | System | 04 Feb 2021 19:19:33 |
| User entered '5' | System | 06 Jan 2021 16:45:15 |
| User entered '4' | System | 01 Dec 2020 15:30:04 |
| User entered '3' | System | 18 Nov 2020 16:24:16 |
| User entered '2' | System | 09 Nov 2020 19:05:39 |
| User entered '1' | System | 28 Oct 2020 17:09:18 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 08:09:56

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered '01/Apr/2021 10:23' | (b) (4) System | 01 Apr 2021 14:23:38 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 08:09:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Apr 2021 18:44:41 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 01 Apr 2021 14:23:38 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'USA-US077-2020-MRNA-1273-P301000006' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Yes (Y)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Yes (Y)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'No (N)' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Evan' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Anderson' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-------------------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered '2015 Uppergate Drive' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'Atlanta' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered 'GA' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 17:09:13 |
| User entered '30323' | System | 28 Oct 2020 17:08:44 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 22:04:15 |
| User signature succeeded. | Evan Anderson (b) (4) | 02 Apr 2021 18:55:04 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 19:05:31 |
| User entered 'US' | System | 28 Oct 2020 17:09:18 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '10' | System | 09 Apr 2021 18:44:54 |
| User entered '9' | System | 01 Apr 2021 14:23:38 |
| User entered '8' | System | 08 Mar 2021 17:04:59 |
| User entered '7' | System | 08 Feb 2021 14:46:50 |
| User entered '6' | System | 04 Feb 2021 19:19:33 |
| User entered '5' | System | 06 Jan 2021 16:45:15 |
| User entered '4' | System | 01 Dec 2020 15:30:04 |
| User entered '3' | System | 18 Nov 2020 16:24:16 |
| User entered '2' | System | 09 Nov 2020 19:05:39 |
| User entered '1' | System | 28 Oct 2020 17:09:18 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 08:09:56

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Evan Anderson (b) (4) | 16 Apr 2021 08:40:02 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 15 Apr 2021 21:25:57 |
| User entered '09/Apr/2021 14:44' | System | 09 Apr 2021 18:44:54 |

US3532281

Folder: SAE USA-US077-2020-MRNA-1273-P301000006

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 08:09:56

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. | Evan Anderson (b) (4) | 16 Apr 2021 08:40:02 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 15 Apr 2021 21:25:57 |
| User entered 'I' | (b) (4), (b) (6) | 09 Apr 2021 18:44:54 |
| | | |