

US3832071 (Prod: Keystone VitaLink Research - Anderson - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:02:20

All time stamps listed in this document are displayed in GMT

US3832071

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

Participant ID

US3832071

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

US3832071

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

| | |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 04 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | SCRN |

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

| | |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Birth (MMM yyyy) | (b) (6) 1961 |
| Age | 58 |
| Age Units | YEARS |
| Age (Derived) | 58 |
| Sex | Female <input checked="" type="radio"/> Male <input type="radio"/> |
| Ethnicity | Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/> |
| Race (Check All That Apply) | |
| White | True |
| Black | False |
| Asian | False |
| American Indian or Alaska Native | False |
| Native Hawaiian or other Pacific Islander | False |
| Other | False |
| If race is Other, specify _____ | |
| Unknown | False |
| Not reported | False |

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

| | |
|-------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 04 AUG 2020 |
| Month and Year of Informed Consent (derived) | AUG 2020 |
| Year of Informed Consent (derived) | 2020 |
| Protocol Version | Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, indicate reason for screen fail | Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/> |
| If reason for screen fail is Other, specify | |
| Was this participant screened previously? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If Yes, previous participant number | |
| Enrollment Trigger | 1 |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 14:04:07

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 14:04:07

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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) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

| | |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition | BREAST CANCER LEFT BREAST |
| Start date (dd MMM yyyy) | UN UNK 2011 |
| 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 2011 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2011 |
| Start Year (derived) | 2011 |
| Stop Month and Year (derived) | JAN 2011 |
| Stop Year (derived) | 2011 |

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 14:04:07

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

| | |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition | OSTEOARTHRITIS |
| Start date (dd MMM yyyy) | UN UNK 1984 |
| 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 1984 |
| Start Year (derived) | 1984 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

| | |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition | ECZEMA (BILATERAL LEGS AND ARMS) |
| Start date (dd MMM yyyy) | UN MAR 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) | MAR 2020 |
| Start Year (derived) | 2020 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Feb 2021 14:04:07

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 15 Feb 2021 14:04:07

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| | |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition | BILATERAL TUBAL LIGATION |
| Start date (dd MMM yyyy) | UN UNK 1982 |
| 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 1982 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1982 |
| Start Year (derived) | 1982 |
| Stop Month and Year (derived) | JAN 1982 |
| Stop Year (derived) | 1982 |

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

| | |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition | L5 S1 HERNIATED DISC |
| Start date (dd MMM yyyy) | UN UNK 2018 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2018 |
| Start Year (derived) | 2018 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

| | |
|-------------------------------------------|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 04 AUG 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 10:52 (24 HR) |
| Vital Signs Date and Time (derived) | 04 AUG 2020 10:52 |
| Height (<i>xxx.x</i>) | 172 cm |
| Weight (<i>xxx.x</i>) | 84.4 kg |
| BMI (<i>xxx.x</i>) | 28.52893 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) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 14:04:07

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Date of assessment (dd MMM yyyy) 04 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☒
Post-menopausal ☐
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 1982

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) _____

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 14:04:07

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 14:04:07

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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 | |

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

| | |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 04 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT1 |

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

What was the date of randomization? (dd MMM yyyy) 04 AUG 2020

What was the participant's randomization number? 142841

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

| | |
|--------|---------------|
| 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) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

| | |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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) | 04 AUG 2020 |
| Time of assessment (00:00-23:59) | 10:52 (24 HR) |
| Vital Signs Date and Time (derived) | 04 AUG 2020 10:52 |
| Temperature (xxx.x) | 97.7 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 71 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 17 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 141 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 87 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

| | |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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) | 04 AUG 2020 |
| Time of assessment (00:00-23:59) | 12:06 (24 HR) |
| Vital Signs Date and Time (derived) | 04 AUG 2020 12:06 |
| Temperature (xxx.x) | 97.2 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 73 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 156 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 86 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

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) 04 AUG 2020

What was the treatment time? (00:00-23:59) 11:34 (24 HR)

Treatment Date and Time (derived) 04 AUG 2020 11:34

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 AUG 2020

Collection time (00:00-23:59)

11:33 (24 HR)

Collection date and time (derived)

04 AUG 2020 11:33

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 04 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 11:22 | 04 AUG 2020 11:22 |
| Nasopharyngeal Swab 2 | No | | |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

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 10:02:20

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

97.2 °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

04 AUG 2020 12:08

PC Open Date & Time

04 AUG 2020 11:54

PC Close Date & Time

04 AUG 2020 14:24

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

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 95.9 °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 | 04 AUG 2020 22:41 |
| PC Open Date & Time | 04 AUG 2020 15:19 |
| PC Close Date & Time | 05 AUG 2020 11:59 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:02:20

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

98.1 °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

05 AUG 2020 17:22

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:02:20

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

97.1 °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

06 AUG 2020 22:00

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °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

07 AUG 2020 22:19

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

08 AUG 2020 23:03

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:02:20

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

97.6 °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

10 AUG 2020 22:33

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

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

04 AUG 2020 12:09

PC Open Date & Time

04 AUG 2020 11:54

PC Close Date & Time

04 AUG 2020 14:24

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

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

04 AUG 2020 22:43

PC Open Date & Time

04 AUG 2020 15:19

PC Close Date & Time

05 AUG 2020 11:59

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:02:20

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

05 AUG 2020 17:23

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:02:20

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

06 AUG 2020 22:01

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:02:20

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

07 AUG 2020 22:19

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:02:20

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

08 AUG 2020 23:04

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:02:20

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

10 AUG 2020 22:34

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

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 ☐

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 04 AUG 2020 12:09 |
| PC Open Date & Time | 04 AUG 2020 11:54 |
| PC Close Date & Time | 04 AUG 2020 14:24 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

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 ☐

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 04 AUG 2020 22:43 |
| PC Open Date & Time | 04 AUG 2020 15:19 |
| PC Close Date & Time | 05 AUG 2020 11:59 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

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 ☒

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 05 AUG 2020 17:24 |
| PC Open Date & Time | 05 AUG 2020 12:00 |
| PC Close Date & Time | 06 AUG 2020 11:59 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

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 ☒

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 06 AUG 2020 22:01 |
| PC Open Date & Time | 06 AUG 2020 12:00 |
| PC Close Date & Time | 07 AUG 2020 11:59 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

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 ☒

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 07 AUG 2020 22:20 |
| PC Open Date & Time | 07 AUG 2020 12:00 |
| PC Close Date & Time | 08 AUG 2020 11:59 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

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 ☒

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 08 AUG 2020 23:05 |
| PC Open Date & Time | 08 AUG 2020 12:00 |
| PC Close Date & Time | 09 AUG 2020 11:59 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

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 ☐

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

Yes ☐

PC Time stamp

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

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 ☒

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 10 AUG 2020 22:34 |
| PC Open Date & Time | 10 AUG 2020 12:00 |
| PC Close Date & Time | 11 AUG 2020 11:59 |

US3832071

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832071

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832071

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:01:13

Generated On: 10 Jun 2021 10:02:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832071

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:01:09

Generated On: 10 Jun 2021 10:02:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832071

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:01:13

Generated On: 10 Jun 2021 10:02:20

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 AUG 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832071

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:01:13

Generated On: 10 Jun 2021 10:02:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832071

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

| | |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 1 SEP 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT2 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

| | |
|-------------------------------------|-------------------------------------------|
| 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) | 1 SEP 2020 |
| Time of assessment (00:00-23:59) | 09:29 (24 HR) |
| Vital Signs Date and Time (derived) | 1 SEP 2020 09:29 |
| Temperature (xxx.x) | 97.4 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 75 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 17 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 131 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 84 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

| | |
|-------------------------------------|-----------------------------------------------|
| 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) | 1 SEP 2020 |
| Time of assessment (00:00-23:59) | 10:27 (24 HR) |
| Vital Signs Date and Time (derived) | 1 SEP 2020 10:27 |
| Temperature (xxx.x) | 97.4 F |
| Route of measurement | Oral <input checked="" type="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 76 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 145 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 86 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 SEP 2020

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

US3832071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

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) 1 SEP 2020

What was the treatment time? (00:00-23:59) 09:57 (24 HR)

Treatment Date and Time (derived) 1 SEP 2020 09:57

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

US3832071

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

1 SEP 2020

Collection time (00:00-23:59)

09:45 (24 HR)

Collection date and time (derived)

1 SEP 2020 09:45

US3832071

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

| Collection date (dd MMM yyyy) | | | 1 SEP 2020 |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 09:41 | 1 SEP 2020 09:41 |
| Nasopharyngeal Swab 2 | No | | |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

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

97.4 °F

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

Yes ☐
No ☒

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

PC Time Stamp 01 SEP 2020 10:31

PC Open Date & Time 01 SEP 2020 10:17

PC Close Date & Time 01 SEP 2020 12:47

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

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 97.1 °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 | 01 SEP 2020 21:52 |
| PC Open Date & Time | 01 SEP 2020 13:42 |
| PC Close Date & Time | 02 SEP 2020 11:59 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

02 SEP 2020 22:17

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:02:20

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 21:41

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 21:19

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °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

05 SEP 2020 23:23

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 23:50

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:02:20

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 08:39

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

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

01 SEP 2020 10:32

PC Open Date & Time

01 SEP 2020 10:17

PC Close Date & Time

01 SEP 2020 12:47

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

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

01 SEP 2020 21:53

PC Open Date & Time

01 SEP 2020 13:42

PC Close Date & Time

02 SEP 2020 11:59

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:02:20

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

02 SEP 2020 22:18

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:02:20

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

03 SEP 2020 21:42

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:02:20

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

04 SEP 2020 21:19

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:02:20

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

05 SEP 2020 23:23

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:02:20

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

06 SEP 2020 23:50

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:02:20

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

08 SEP 2020 08:39

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

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 ☐

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 01 SEP 2020 10:33 |
| PC Open Date & Time | 01 SEP 2020 10:17 |
| PC Close Date & Time | 01 SEP 2020 12:47 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

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 ☐

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 01 SEP 2020 21:54 |
| PC Open Date & Time | 01 SEP 2020 13:42 |
| PC Close Date & Time | 02 SEP 2020 11:59 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

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

101 of 2019

EAB) (1725)

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 02 SEP 2020 22:19 |
| PC Open Date & Time | 02 SEP 2020 12:00 |
| PC Close Date & Time | 03 SEP 2020 11:59 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

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 ☒

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 03 SEP 2020 21:42 |
| PC Open Date & Time | 03 SEP 2020 12:00 |
| PC Close Date & Time | 04 SEP 2020 11:59 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

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 ☒

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 04 SEP 2020 21:20 |
| PC Open Date & Time | 04 SEP 2020 12:00 |
| PC Close Date & Time | 05 SEP 2020 11:59 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

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 ☒

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 05 SEP 2020 23:24 |
| PC Open Date & Time | 05 SEP 2020 12:00 |
| PC Close Date & Time | 06 SEP 2020 11:59 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

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 ☒

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 06 SEP 2020 23:51 |
| PC Open Date & Time | 06 SEP 2020 12:00 |
| PC Close Date & Time | 07 SEP 2020 11:59 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

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)

111 of 2019

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 08 SEP 2020 08:40 |
| PC Open Date & Time | 07 SEP 2020 12:00 |
| PC Close Date & Time | 08 SEP 2020 11:59 |

US3832071

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:01:13

Generated On: 10 Jun 2021 10:02:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832071

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:01:13

Generated On: 10 Jun 2021 10:02:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832071

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832071

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832071

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832071

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832071

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

| | |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 29 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 | VISIT3 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 29 SEP 2020 |
| Time of assessment (00:00-23:59) | 09:52 (24 HR) |
| Vital Signs Date and Time (derived) | 29 SEP 2020 09:52 |
| Temperature (xxx.x) | 97.6 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 78 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 130 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 83 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3832071

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 29 SEP 2020 |
| Collection time (00:00-23:59) | 10:10 (24 HR) |
| Collection date and time (derived) | 29 SEP 2020 10:10 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:04:07

Generated On: 10 Jun 2021 10:02:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| TIMEPOINT | DAY 64 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 07 OCT 2020 14:23:39 |
| Patient Cloud Open Date & Time | 04 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 08 OCT 2020 23:59 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

13 OCT 2020 09:55:53

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 13:14:02

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 NOV 2020 12:00:33

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| TIMEPOINT | DAY 99 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 NOV 2020 14:50:51 |
| Patient Cloud Open Date & Time | 08 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 12 NOV 2020 23:59 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| TIMEPOINT | DAY 106 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| 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 | 17 NOV 2020 11:18:05 |
| Patient Cloud Open Date & Time | 15 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 19 NOV 2020 23:59 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

30 NOV 2020 10:32:41

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 DEC 2020 10:31:49

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

10 DEC 2020 13:09:39

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

20 DEC 2020 16:18:09

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

24 DEC 2020 20:22:18

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 11:26:26

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| TIMEPOINT | DAY 159 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 | 07 JAN 2021 22:56:35 |
| Patient Cloud Open Date & Time | 07 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 11 JAN 2021 23:59 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 12:54:30

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

21 JAN 2021 11:16:03

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| 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 | 01 FEB 2021 19:25:18 |
| Patient Cloud Open Date & Time | 28 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 01 FEB 2021 23:59 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

05 FEB 2021 14:03:54

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| TIMEPOINT | DAY 194 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 | 11 FEB 2021 13:15:25 |
| Patient Cloud Open Date & Time | 11 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 15 FEB 2021 23:59 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 14:16:55

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

26 FEB 2021 11:37:37

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

05 MAR 2021 09:57:32

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| 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 <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 MAR 2021 16:13:37 |
| Patient Cloud Open Date & Time | 11 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 15 MAR 2021 23:59 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

19 MAR 2021 10:03:43

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| 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 | 25 MAR 2021 14:58:56 |
| Patient Cloud Open Date & Time | 25 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 29 MAR 2021 23:59 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 12:25:53

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 05:12:47

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 14:39:52

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 12:17:02

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 10:04:16

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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 ☐

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| 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 <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"/> |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| 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="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"/> |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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 ☐

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| 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"/> |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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 ☐

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 362

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| 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 <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"/> |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

| | |
|----------------------------------------------------|-------------------|
| Patient Cloud Open Date & Time | 12 AUG 2021 00:01 |
|----------------------------------------------------|-------------------|

| | |
|-----------------------------------------------------|-------------------|
| Patient Cloud Close Date & Time | 16 AUG 2021 23:59 |
|-----------------------------------------------------|-------------------|

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| TIMEPOINT | DAY 383 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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°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 ☐

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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 ☐

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| 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"/> |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| 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"/> |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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 ☐

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| 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 <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"/> |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| 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"/> |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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 ☐

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| 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="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"/> |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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 ☐

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

| | |
|----------------------------------------------------|-------------------|
| Patient Cloud Open Date & Time | 23 DEC 2021 00:01 |
|----------------------------------------------------|-------------------|

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| Patient Cloud Close Date & Time | 27 DEC 2021 23:59 |
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US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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 ☐

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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 ☐

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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 ☐

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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 ☐

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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 ☐

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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 ☐

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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 ☐

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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 ☐

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| 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"/> |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| 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°F/38°C) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| TIMEPOINT | DAY 628 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature \geq 100.4°F/38°C) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| 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 <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"/> |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| TIMEPOINT | DAY 642 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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 ☐

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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°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 ☐

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| 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"/> |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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 ☐

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| 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"/> |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| 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"/> |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| TIMEPOINT | DAY 726 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 733

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| 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"/> |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 747

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

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

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

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

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

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

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

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| 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 <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"/> |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

| | |
|----------------------------------------------------|-------------------|
| Patient Cloud Open Date & Time | 25 AUG 2022 00:01 |
|----------------------------------------------------|-------------------|

| | |
|-----------------------------------------------------|-------------------|
| Patient Cloud Close Date & Time | 29 AUG 2022 23:59 |
|-----------------------------------------------------|-------------------|

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| 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"/> |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| 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 <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"/> |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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 ☐

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| 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 <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"/> |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

| 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"/> |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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

| | |
|-----------------------------------------------------|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 06 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 10 OCT 2022 23:59 |

US3832071

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:02:20

| Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other? | Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache? | Date & Time of Submission |
|-------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| No | | 05 MAR 2021 09:57:50 |

US3832071

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:01:13

Generated On: 10 Jun 2021 10:02:20

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

US3832071

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:01:13

Generated On: 10 Jun 2021 10:02:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832071

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:01:09

Generated On: 10 Jun 2021 10:02:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832071

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:01:09

Generated On: 10 Jun 2021 10:02:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832071

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:01:09

Generated On: 10 Jun 2021 10:02:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832071

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:01:09

Generated On: 10 Jun 2021 10:02:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832071

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:01:13

Generated On: 10 Jun 2021 10:02:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832071

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:01:13

Generated On: 10 Jun 2021 10:02:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832071

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Mar 2021 12:07:01

Generated On: 10 Jun 2021 10:02:20

| | |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 2 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 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 23:03:15

Generated On: 10 Jun 2021 10:02:20

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) _____

US3832071

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Mar 2021 12:07:01

Generated On: 10 Jun 2021 10:02:20

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.

US3832071

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Mar 2021 12:07:01

Generated On: 10 Jun 2021 10:02:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 MAR 2021

Collection time (00:00-23:59)

10:15 (24 HR)

Collection date and time (derived)

2 MAR 2021 10:15

US3832071

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 12:07:01

Generated On: 10 Jun 2021 10:02:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832071

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 02:19:20

Generated On: 10 Jun 2021 10:02:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832071

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 02:19:20

Generated On: 10 Jun 2021 10:02:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832071

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 02:19:20

Generated On: 10 Jun 2021 10:02:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832071

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 02:19:20

Generated On: 10 Jun 2021 10:02:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832071

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

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

US3832071

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3832071

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:02:20

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

US3832071

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:02:20

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3832071

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

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:01:09

Generated On: 10 Jun 2021 10:02:20

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

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

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 23:03:14

Generated On: 10 Jun 2021 10:02:20

Date of updated informed consent (dd MMM yyyy) 28 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) 28 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) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 JAN 2021

Collection time (00:00-23:59)

15:49 (24 HR)

Collection date and time (derived)

28 JAN 2021 15:49

US3832071

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 28 JAN 2021 |
| Collection time (00:00 - 23:59) | 15:53 |
| Collection Date and Time (derived) | 28 JAN 2021 15:53 |

US3832071

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Apr 2021 23:03:14

Generated On: 10 Jun 2021 10:02:20

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 02:19:20

Generated On: 10 Jun 2021 10:02:20

| | |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID | USA-US100-2021-MRNA-1273-P30 1000010 |
| Adverse event | RUPTURED APPENDIX |
| Was this a medically-attended AE? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Start date (dd MMM yyyy) | 21 MAR 2021 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 27 MAR 2021 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input 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) | 26 MAR 2021 |
| Hospital Discharge Date (dd MMM yyyy) | 31 MAR 2021 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 02:19:20

Generated On: 10 Jun 2021 10:02:20

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

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 02:19:20

Generated On: 10 Jun 2021 10:02:20

SUBJECT CONTACTED FOR
DAY 239 SUBJECT, REPORTS
THAT ON 3/26/2021 THAT SHE
WAS ADMITTED TO THE
HOSPITAL FOR A RUPTURED
APPENDIX SUBJECT STATES
SHE HAD SURGERY ON
3/27/2021 FOR AN
APPENDICECTOMY. SUBJECT
WAS DISCHARGED 3/31/2021.
SUBJECT IS UNSURE OF
MEDICATIONS. A MEDICAL
RECORDS RELEASE HAS BEEN
SENT TO THE SUBJECT TO
RECEIVE RECORDS.

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

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

Yes ☒

No ☐

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

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

Name of Medication BEVESPI AEROSPHERE

Prophylaxis Yes ☐
No ☒

Indication COPD - CHRONIC
OBSTRUCTIVE PULMONARY
DISEASE

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

| | | |
|------------------------------------------------|--------------------------|----------------------------------|
| | Intraocular | <input type="radio"/> |
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input checked="" type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify | | |
| Start date (dd MMM yyyy) | UN APR 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 2 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication CHRONIC NAUSEA

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

Name of Medication VITAMIN D3

Prophylaxis Yes ☐
No ☒

Indication LOW VITAMIN D

Dose per administration 50000

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) 21 Feb 2021 17:01:08

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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 MAY 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 checked="" type="radio"/> |
| | 804 | <input type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD - GASTROESOPHAGEAL
REFLUX DISEASE

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

| | | |
|----------------------------------------------------|--------------------------|----------------------------------|
| | 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 (6)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

Name of Medication ALBUTEROL SULFATE

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

| | | |
|------------------------------------------------|--------------------------|-------------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input checked="" type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify | | |
| Start date (dd MMM yyyy) | UN UNK 2015 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="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 (7)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

Name of Medication VENTOLIN

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Dose per administration 90

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
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

| | | |
|------------------------------------------------|--------------------------|-------------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input checked="" type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify | | |
| Start date (dd MMM yyyy) | UN UNK 2015 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="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 (8)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

Name of Medication TRAZODONE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

350 of 2019

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

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

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

Name of Medication CELECOXIB

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

352 of 2019

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

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

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

Name of Medication CLOBETASOL PROPIONATE

Prophylaxis Yes ☐
No ☒

Indication ECZEMA

Dose per administration 0.05

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

If dose unit is Other, specify PERCENT %

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)

354 of 2019

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

| | | |
|----------------------------------------------------|--------------------------|----------------------------------|
| | 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 JUL 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 2 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

Name of Medication VORTIOXETINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

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

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

Name of Medication PREGABALIN

Prophylaxis Yes ☐
No ☒

Indication FIBROMYALGIA

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

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

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

Name of Medication _____

Prophylaxis Yes ☐
No ☐

Indication _____

Dose per administration _____

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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US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

| | | |
|----------------------------------------------------|--------------------------|--------------------------|
| | 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 _____ | | |
| Ongoing? | Yes | <input 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 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"/> |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

Name of Medication _____

Prophylaxis Yes ☐
No ☐

Indication _____

Dose per administration _____

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 ☐

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

| | | |
|----------------------------------------------------|--------------------------|--------------------------|
| | 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 _____ | | |
| Ongoing? | Yes | <input 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 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"/> |

US3832071

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Feb 2021 17:01:08

Generated On: 10 Jun 2021 10:02:20

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3832071

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Apr 2021 23:03:14

Generated On: 10 Jun 2021 10:02:20

| Procedure/Surgery date (dd MMM yyyy) | Procedure/Surgery | Indication | If indication is Other, specify |
|-----------------------------------------|-----------------------------|-----------------|---------------------------------|
| 1 DEC 2020 | L5 S1 HERNIATED DISC REPAIR | Medical History | |
| 27 MAR 2021 | APPENDECTOMY | Adverse Event | |

US3832071

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:02:20

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

US3832071

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:02:20

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 ☐

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 02:19:20

Generated On: 10 Jun 2021 10:02:20

| | |
|----------------------------------------------------------------|------------------------------------------------------------------|
| SAEID | USA-US100-2021-MRNA-1273-P301000010 |
| 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 | GOWDHAMI |
| Investigator's Last Name | MOHAN |
| Site Address: Street | 1655 E. GREENVILLE ST |
| Site Address: City | ANDERSON |
| Site Address: State | SC |
| Site Address: Postal Code | 29621 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 2 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 02:19:20

Generated On: 10 Jun 2021 10:02:20

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID | USA-US100-2021-MRNA-1273-P301000010 |
| 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 | GOWDHAMI |
| Investigator's Last Name | MOHAN |
| Site Address: Street | 1655 E. GREENVILLE ST |
| Site Address: City | ANDERSON |
| Site Address: State | SC |
| Site Address: Postal Code | 29621 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 2 |
| Date of submission (Pre-filled from custom function) | 02/APR/2021 09:03 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 02:19:20

Generated On: 10 Jun 2021 10:02:20

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID | USA-US100-2021-MRNA-1273-P301000010 |
| 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 | GOWDHAMI |
| Investigator's Last Name | MOHAN |
| Site Address: Street | 1655 E. GREENVILLE ST |
| Site Address: City | ANDERSON |
| Site Address: State | SC |
| Site Address: Postal Code | 29621 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 2 |
| Date of submission (Pre-filled from custom function) | 26/APR/2021 11:56 |
| 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. | True |

Audit

US3832071 (Prod: Keystone VitaLink Research - Anderson - PPDS)

US3832071

Form: Participant Creation

Generated On: 10 Jun 2021 10:02:20

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 29 Oct 2020 01:18:33 |
| User entered 'US3832071' | RWS_ENDPOINT ENDPOINT (b) (4) | 04 Aug 2020 14:29:28 |

US3832071

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:02:20

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:17:57 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:34:32 |

US3832071

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 15:17:57 |
| User entered '04 AUG 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 04 Aug 2020 14:29:28 |

US3832071

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:17:57 |
| User entered 'Clinic (Clinic)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:34:32 |

US3832071

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:02:20

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'SCRN' | System | 04 Aug 2020 15:34:32 |

US3832071

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:02:20

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 15:18:16 |
| User entered (b) (6) 1961' | RWS_ENDPOINT ENDPOINT (b) (4) | 04 Aug 2020 14:29:29 |

US3832071

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:02:20

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:18:16 |
| User entered '58' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:34:48 |

US3832071

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:02:20

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'YEARS' | System | 04 Aug 2020 15:34:48 |

US3832071

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:02:20

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered '58' | System | 04 Aug 2020 15:35:13 |

US3832071

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:02:20

[Sex](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:18:16 |
| User entered 'Female (F)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:34:48 |

US3832071

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:02:20

[Ethnicity](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:18:16 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:34:48 |

US3832071

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:02:20

[White](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:18:16 |
| User entered 'l' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:34:48 |

US3832071

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:02:20

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:18:16 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:34:48 |

US3832071

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:02:20

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:18:16 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:34:48 |

US3832071

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:02:20

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:18:16 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:34:48 |

US3832071

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:02:20

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:18:16 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:34:48 |

US3832071

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:02:20

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:18:16 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:34:48 |

US3832071

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:02:20

[If race is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:18:16 |
| User entered empty. | Ashten Sheriff (b) (4) | 04 Aug 2020 15:34:48 |

US3832071

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:02:20

[Unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:18:16 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:34:48 |

US3832071

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:02:20

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:18:16 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:34:48 |

US3832071

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:02:20

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:10:46 |
| User entered '04 Aug 2020' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:35:13 |

US3832071

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'Aug 2020' | System | 04 Aug 2020 15:35:13 |

US3832071

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered '2020' | System | 04 Aug 2020 15:35:13 |

US3832071

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:02:20

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:10:46 |
| User entered 'Amendment 1 (1)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:35:13 |

US3832071

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:10:46 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:35:13 |

US3832071

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:10:46 |
| User entered empty. | Ashten Sheriff (b) (4) | 04 Aug 2020 15:35:13 |

US3832071

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:02:20

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:10:46 |
| User entered empty. | Ashten Sheriff (b) (4) | 04 Aug 2020 15:35:13 |

US3832071

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:02:20

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:10:46 |
| User entered 'No (N)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:35:13 |

US3832071

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:02:20

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 15:10:46 |
| User entered empty. | RWS_ENDPOINT ENDPOINT (b) (4) | 04 Aug 2020 14:29:28 |

US3832071

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:02:20

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'I' | System | 04 Aug 2020 15:35:20 |

US3832071

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:21:20 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:35:20 |

US3832071

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:02:20

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:21:27 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:35:32 |

US3832071

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:02:20

Condition

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer, LLT: Breast cancer - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 04 Aug 2020 16:05:56 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 04 Aug 2020 16:05:56 |
| Data point term sent to Coder | System | 04 Aug 2020 15:36:44 |
| User entered 'Breast Cancer Left Breast' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:36:11 |

US3832071

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered 'un UNK 2011' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:36:11 |

US3832071

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:02:20

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:36:11 |

US3832071

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:02:20

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered 'No (N)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:36:11 |

US3832071

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered 'un UNK 2011' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:36:11 |

US3832071

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:02:20

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:36:11 |

US3832071

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'Jan 2011' | System | 04 Aug 2020 15:36:11 |

US3832071

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered '2011' | System | 04 Aug 2020 15:36:11 |

US3832071

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'Jan 2011' | System | 04 Aug 2020 15:36:11 |

US3832071

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered '2011' | System | 04 Aug 2020 15:36:11 |

US3832071

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:02:20

Condition

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer, LLT: Breast cancer - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 04 Aug 2020 16:06:59 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 04 Aug 2020 16:06:59 |
| Data point term sent to Coder | System | 04 Aug 2020 15:36:45 |
| User entered 'Breast Cancer R Breast' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:36:39 |

US3832071

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered 'un UNK 2000' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:36:39 |

US3832071

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:02:20

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:36:39 |

US3832071

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:02:20

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered 'No (N)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:36:39 |

US3832071

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered 'un UNK 2000' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:36:39 |

US3832071

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:02:20

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:36:39 |

US3832071

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'Jan 2000' | System | 04 Aug 2020 15:36:39 |

US3832071

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered '2000' | System | 04 Aug 2020 15:36:39 |

US3832071

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'Jan 2000' | System | 04 Aug 2020 15:36:39 |

US3832071

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered '2000' | System | 04 Aug 2020 15:36:39 |

US3832071

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:02:20

Condition

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 04 Aug 2020 15:39:07 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 04 Aug 2020 15:39:07 |
| Data point term sent to Coder | System | 04 Aug 2020 15:37:48 |
| User entered 'Chronic Obstructive Pulmonary Disease' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:37:09 |

US3832071

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered 'un UNK 2015' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:37:09 |

US3832071

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:02:20

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:37:09 |

US3832071

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:02:20

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:37:09 |

US3832071

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered empty. | Ashten Sheriff (b) (4) | 04 Aug 2020 15:37:09 |

US3832071

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:02:20

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:37:09 |

US3832071

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'Jan 2015' | System | 04 Aug 2020 15:37:09 |

US3832071

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered '2015' | System | 04 Aug 2020 15:37:09 |

US3832071

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered empty. | System | 04 Aug 2020 15:37:09 |

US3832071

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered empty. | System | 04 Aug 2020 15:37:09 |

US3832071

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:02:20

Condition

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User closed query 'Per MM: Please review and update the term to reflect the final diagnosis. ' (Site from DM). | (b) (4), (b) (6) | 29 Sep 2020 12:11:43 |
| Query 'Per MM: Please review and update the term to reflect the final diagnosis. ' answered with 'Per subject report no noted diagnosis' (Site from DM). | Danyel Johnson (b) (4) (b) (4) | 23 Sep 2020 17:06:32 |
| User opened query 'Per MM: Please review and update the term to reflect the final diagnosis. ' (Site from DM). | (b) (4), (b) (6) | 15 Sep 2020 13:38:13 |
| User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 04 Aug 2020 16:08:07 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 04 Aug 2020 16:08:07 |
| Data point term sent to Coder | System | 04 Aug 2020 15:37:46 |
| User entered 'Chronic Nausea' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:37:27 |

US3832071

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered 'un UNK 2018' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:37:27 |

US3832071

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:02:20

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:37:27 |

US3832071

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:02:20

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:37:27 |

US3832071

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered empty. | Ashten Sheriff (b) (4) | 04 Aug 2020 15:37:27 |

US3832071

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:02:20

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:37:27 |

US3832071

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'Jan 2018' | System | 04 Aug 2020 15:37:27 |

US3832071

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered '2018' | System | 04 Aug 2020 15:37:27 |

US3832071

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered empty. | System | 04 Aug 2020 15:37:27 |

US3832071

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered empty. | System | 04 Aug 2020 15:37:27 |

US3832071

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:02:20

Condition

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User coded data point as SOC: Investigations, HLGT: Metabolic, nutritional and blood gas investigations, HLT: Vitamin analyses, PT: Vitamin D decreased, LLT: Vitamin D low - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 04 Aug 2020 15:39:07 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 04 Aug 2020 15:39:07 |
| Data point term sent to Coder | System | 04 Aug 2020 15:37:48 |
| User entered 'Low Vitamin D' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:37:41 |

US3832071

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered 'un UNK 2017' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:37:41 |

US3832071

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:02:20

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:37:41 |

US3832071

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:02:20

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:37:41 |

US3832071

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered empty. | Ashten Sheriff (b) (4) | 04 Aug 2020 15:37:41 |

US3832071

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:02:20

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:37:41 |

US3832071

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'Jan 2017' | System | 04 Aug 2020 15:37:41 |

US3832071

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered '2017' | System | 04 Aug 2020 15:37:41 |

US3832071

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered empty. | System | 04 Aug 2020 15:37:41 |

US3832071

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered empty. | System | 04 Aug 2020 15:37:41 |

US3832071

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:02:20

Condition

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 04 Aug 2020 15:40:10 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 04 Aug 2020 15:40:10 |
| Data point term sent to Coder | System | 04 Aug 2020 15:38:48 |
| User entered 'Gastroesophageal Reflux Disease' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:38:02 |

US3832071

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered 'un UNK 2016' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:38:02 |

US3832071

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:02:20

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:38:02 |

US3832071

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:02:20

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:38:02 |

US3832071

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered empty. | Ashten Sheriff (b) (4) | 04 Aug 2020 15:38:02 |

US3832071

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:02:20

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:38:02 |

US3832071

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'Jan 2016' | System | 04 Aug 2020 15:38:02 |

US3832071

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered '2016' | System | 04 Aug 2020 15:38:02 |

US3832071

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered empty. | System | 04 Aug 2020 15:38:02 |

US3832071

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered empty. | System | 04 Aug 2020 15:38:02 |

US3832071

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:02:20

Condition

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 04 Aug 2020 15:40:10 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 04 Aug 2020 15:40:10 |
| Data point term sent to Coder | System | 04 Aug 2020 15:38:50 |
| User entered 'Hypothyroidism' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:38:19 |

US3832071

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered 'un UNK 2016' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:38:19 |

US3832071

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:02:20

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:38:19 |

US3832071

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:02:20

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:38:19 |

US3832071

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered empty. | Ashten Sheriff (b) (4) | 04 Aug 2020 15:38:19 |

US3832071

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:02:20

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:38:19 |

US3832071

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'Jan 2016' | System | 04 Aug 2020 15:38:19 |

US3832071

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered '2016' | System | 04 Aug 2020 15:38:19 |

US3832071

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered empty. | System | 04 Aug 2020 15:38:19 |

US3832071

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered empty. | System | 04 Aug 2020 15:38:19 |

US3832071

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:02:20

[Condition](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| 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) (b) (4) | 04 Aug 2020 15:40:09 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 04 Aug 2020 15:40:09 |
| Data point term sent to Coder | System | 04 Aug 2020 15:38:50 |
| User entered 'Depression' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:38:30 |

US3832071

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered 'un UNK 2000' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:38:30 |

US3832071

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:02:20

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:38:30 |

US3832071

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:02:20

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:38:30 |

US3832071

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered empty. | Ashten Sheriff (b) (4) | 04 Aug 2020 15:38:30 |

US3832071

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:02:20

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:38:30 |

US3832071

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'Jan 2000' | System | 04 Aug 2020 15:38:30 |

US3832071

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered '2000' | System | 04 Aug 2020 15:38:30 |

US3832071

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered empty. | System | 04 Aug 2020 15:38:30 |

US3832071

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered empty. | System | 04 Aug 2020 15:38:30 |

US3832071

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:02:20

Condition

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 29 Oct 2020 01:40:52 |
| 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) (b) (4) | 21 Oct 2020 17:04:45 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Oct 2020 17:04:45 |
| Data point term sent to Coder | System | 21 Oct 2020 17:03:35 |
| DataPoint Un-verified. | Alyssa-Kay Peay (b) (4) (b) (4) | 21 Oct 2020 17:02:53 |
| Coding entries removed. | Alyssa-Kay Peay (b) (4) (b) (4) | 21 Oct 2020 17:02:53 |
| User entered 'osteoARTHRITIS' reason for change: Per Query Resolution | Alyssa-Kay Peay (b) (4) (b) (4) | 21 Oct 2020 17:02:53 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 04 Aug 2020 15:40:10 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 04 Aug 2020 15:40:10 |
| Data point term sent to Coder | System | 04 Aug 2020 15:38:50 |
| User entered 'Arthritis' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:38:47 |

US3832071

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered 'un UNK 1984' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:38:47 |

US3832071

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:02:20

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:38:47 |

US3832071

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:02:20

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:38:47 |

US3832071

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered empty. | Ashten Sheriff (b) (4) | 04 Aug 2020 15:38:47 |

US3832071

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:02:20

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:38:47 |

US3832071

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'Jan 1984' | System | 04 Aug 2020 15:38:47 |

US3832071

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered '1984' | System | 04 Aug 2020 15:38:47 |

US3832071

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered empty. | System | 04 Aug 2020 15:38:47 |

US3832071

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered empty. | System | 04 Aug 2020 15:38:47 |

US3832071

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:02:20

[Condition](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User closed query 'Per MM, please specify the location .' (Site from DM). | (b) (4), (b) (6) | 29 Sep 2020 12:08:56 |
| User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 23 Sep 2020 20:46:42 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 23 Sep 2020 20:46:42 |
| Query 'Per MM, please specify the location .' answered with 'Updated per subject report' (Site from DM). | Danyel Johnson (b) (4) (b) (4) | 23 Sep 2020 17:08:14 |
| Data point term sent to Coder | System | 23 Sep 2020 17:08:04 |
| Coding entries removed. | Danyel Johnson (b) (4) (b) (4) | 23 Sep 2020 17:07:41 |
| User entered 'ECZEMA (Bilateral legs and Arms)' reason for change: Data Entry Error | Danyel Johnson (b) (4) (b) (4) | 23 Sep 2020 17:07:41 |
| User opened query 'Per MM, please specify the location .' (Site from DM). | (b) (4), (b) (6) | 15 Sep 2020 10:20:50 |
| User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 04 Aug 2020 15:40:57 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 04 Aug 2020 15:40:57 |
| Data point term sent to Coder | System | 04 Aug 2020 15:39:51 |
| User entered 'Eczema' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:39:02 |

US3832071

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered 'un Mar 2020' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:39:02 |

US3832071

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:02:20

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:39:02 |

US3832071

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:02:20

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:39:02 |

US3832071

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered empty. | Ashten Sheriff (b) (4) | 04 Aug 2020 15:39:02 |

US3832071

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:02:20

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:39:02 |

US3832071

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'Mar 2020' | System | 04 Aug 2020 15:39:02 |

US3832071

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered '2020' | System | 04 Aug 2020 15:39:02 |

US3832071

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered empty. | System | 04 Aug 2020 15:39:02 |

US3832071

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered empty. | System | 04 Aug 2020 15:39:02 |

US3832071

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:02:20

[Condition](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Fibromyalgia, LLT: Fibromyalgia - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 04 Aug 2020 15:40:57 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 04 Aug 2020 15:40:57 |
| Data point term sent to Coder | System | 04 Aug 2020 15:39:51 |
| User entered 'Fibromyalgia' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:39:16 |

US3832071

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered 'un UNK 2000' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:39:16 |

US3832071

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:02:20

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:39:16 |

US3832071

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:02:20

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:39:16 |

US3832071

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered empty. | Ashten Sheriff (b) (4) | 04 Aug 2020 15:39:16 |

US3832071

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:02:20

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:22:21 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:39:16 |

US3832071

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'Jan 2000' | System | 04 Aug 2020 15:39:16 |

US3832071

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered '2000' | System | 04 Aug 2020 15:39:16 |

US3832071

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered empty. | System | 04 Aug 2020 15:39:16 |

US3832071

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered empty. | System | 04 Aug 2020 15:39:16 |

US3832071

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:02:20

[Condition](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 29 Oct 2020 01:41:24 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 20 Oct 2020 19:13:40 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 20 Oct 2020 19:13:40 |
| Data point term sent to Coder | System | 20 Oct 2020 19:10:10 |
| User entered 'Bilateral Tubal Ligation' | Alyssa-Kay Peay (b) (4) (b) (4) | 20 Oct 2020 19:10:02 |

US3832071

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Oct 2020 01:41:28 |
| User entered 'UN UNK 1982' | Alyssa-Kay Peay (b) (4) | 20 Oct 2020 19:10:02 |

US3832071

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:02:20

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Oct 2020 01:41:26 |
| User entered '0' | Alyssa-Kay Peay (b) (4) | 20 Oct 2020 19:10:02 |

US3832071

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:02:20

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Oct 2020 01:41:31 |
| User entered 'No (N)' | Alyssa-Kay Peay (b) (4) | 20 Oct 2020 19:10:02 |

US3832071

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Oct 2020 01:41:34 |
| User entered 'UN UNK 1982' | Alyssa-Kay Peay (b) (4) | 20 Oct 2020 19:10:02 |

US3832071

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:02:20

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Oct 2020 01:41:36 |
| User entered '0' | Alyssa-Kay Peay (b) (4) | 20 Oct 2020 19:10:02 |

US3832071

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'Jan 1982' | System | 20 Oct 2020 19:10:02 |

US3832071

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered '1982' | System | 20 Oct 2020 19:10:02 |

US3832071

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'Jan 1982' | System | 20 Oct 2020 19:10:02 |

US3832071

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered '1982' | System | 20 Oct 2020 19:10:02 |

US3832071

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:02:20

Condition

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Lumbosacral disc herniation - version MedDRA\\23.0. | Coder Import (b) (4) | 09 Dec 2020 13:10:00 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 09 Dec 2020 13:10:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Dec 2020 19:53:08 |
| Data point term sent to Coder | System | 03 Dec 2020 16:54:28 |
| User entered 'L5 S1 Herniated Disc' | Alyssa-Kay Peay (b) (4) | 03 Dec 2020 16:53:38 |

US3832071

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Dec 2020 19:53:12 |
| User entered 'UN UNK 2018' | Alyssa-Kay Peay (b) (4) | 03 Dec 2020 16:53:38 |

US3832071

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:02:20

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Dec 2020 19:53:10 |
| User entered '0' | Alyssa-Kay Peay (b) (4) | 03 Dec 2020 16:53:38 |

US3832071

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:02:20

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Dec 2020 19:53:15 |
| User closed query 'Per source, condition was ongoing at time of study entry. Please confirm and update.' (Site from CRA). | (b) (4), (b) (6) | 08 Dec 2020 19:51:47 |
| Query 'Per source, condition was ongoing at time of study entry. Please confirm and update.' answered with 'Updated' (Site from CRA). | Danyel Johnson (b) (4) | 07 Dec 2020 14:59:28 |
| User entered 'Yes (Y)' reason for change: Per Query Resolution | (b) (4) | 07 Dec 2020 14:59:15 |
| User opened query 'Per source, condition was ongoing at time of study entry. Please confirm and update.' (Site from CRA). | (b) (4), (b) (6) | 03 Dec 2020 21:31:23 |
| User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System). | System | 03 Dec 2020 16:53:48 |
| User entered 'No (N)' reason for change: Per Query Resolution | Alyssa-Kay Peay (b) (4) | 03 Dec 2020 16:53:48 |
| User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System). | System | 03 Dec 2020 16:53:38 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) | 03 Dec 2020 16:53:38 |

US3832071

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:02:20

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Dec 2020 19:53:17 |
| User closed query 'This date is AFTER the study entry date. Please delete. (the surgery was already captured on the concomitant procedure page.)' (Site from CRA). | (b) (4), (b) (6) | 08 Dec 2020 19:51:53 |
| Query 'This date is AFTER the study entry date. Please delete. (the surgery was already captured on the concomitant procedure page.)' answered with 'Updated' (Site from CRA). | Danyel Johnson (b) (4) (b) (4) | 07 Dec 2020 14:59:37 |
| User entered empty; reason for change Data Entry Error | Danyel Johnson (b) (4) (b) (4) | 07 Dec 2020 14:59:15 |
| User opened query 'This date is AFTER the study entry date. Please delete. (the surgery was already captured on the concomitant procedure page.)' (Site from CRA). | (b) (4), (b) (6) | 03 Dec 2020 21:33:26 |
| User entered '1 Dec 2020' | Alyssa-Kay Peay (b) (4) (b) (4) | 03 Dec 2020 16:53:38 |

US3832071

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:02:20

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Dec 2020 19:53:19 |
| User entered '0' | Alyssa-Kay Peay (b) (4) | 03 Dec 2020 16:53:38 |

US3832071

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'Jan 2018' | System | 03 Dec 2020 16:53:38 |

US3832071

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered '2018' | System | 03 Dec 2020 16:53:38 |

US3832071

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered empty. | System | 07 Dec 2020 14:59:15 |
| User entered 'Dec 2020' | System | 03 Dec 2020 16:53:38 |

US3832071

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered empty. | System | 07 Dec 2020 14:59:15 |
| User entered '2020' | System | 03 Dec 2020 16:53:38 |

US3832071

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:27:13 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:40:43 |

US3832071

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:27:13 |
| User entered '04 Aug 2020' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:40:43 |

US3832071

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:27:13 |
| User entered '10:52' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:40:43 |

US3832071

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered '04 Aug 2020 10:52' | System | 04 Aug 2020 15:40:43 |

US3832071

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Height \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:27:13 |
| User entered '172' cm | Ashten Sheriff (b) (4) | 04 Aug 2020 15:40:43 |
| DataPoint set to visible. | System | 04 Aug 2020 15:35:20 |

US3832071

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

Weight (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:27:13 |
| User entered '84.4' kg | Ashten Sheriff (b) (4) | 04 Aug 2020 15:40:43 |
| DataPoint set to visible. | System | 04 Aug 2020 15:35:20 |

US3832071

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

BMI (xxx.x)

| Audit | User | Time (GMT) |
|--------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| Amendment Manager: User entered '28.52893' | System | 16 Sep 2020 23:42:16 |
| User entered '28.5' | System | 04 Aug 2020 15:40:43 |
| DataPoint set to visible. | System | 04 Aug 2020 15:35:20 |

US3832071

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'kg/m2' | System | 04 Aug 2020 15:40:43 |
| DataPoint set to visible. | System | 04 Aug 2020 15:35:20 |

US3832071

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Dec 2020 21:33:59 |
| User closed query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. (Site from CRA). | (b) (4), (b) (6) | 02 Nov 2020 22:05:31 |
| Query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. ' answered with 'UPDATED PER QUERY' (Site from CRA). | Danyel Johnson (b) (4) (b) (4) | 02 Nov 2020 21:36:31 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 02 Nov 2020 21:35:41 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System | 02 Nov 2020 21:35:41 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Danyel Johnson (b) (4) (b) (4) | 02 Nov 2020 21:35:41 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 02 Nov 2020 21:34:16 |
| DataPoint Un-verified. | Danyel Johnson (b) (4) (b) (4) | 02 Nov 2020 21:34:16 |
| User entered empty; reason for change Data Entry Error | Danyel Johnson (b) (4) (b) (4) | 02 Nov 2020 21:34:16 |
| User opened query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. (Site from CRA). | (b) (4), (b) (6) | 29 Oct 2020 01:54:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:27:13 |
| User entered '97.7' F | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:40:43 |

US3832071

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Dec 2020 21:34:05 |
| User closed query 'please delete.' (Site from CRA). | (b) (4), (b) (6) | 02 Nov 2020 22:05:37 |
| Query 'please delete.' answered with 'UPDATED PER QUERY ' (Site from CRA). | Danyel Johnson (b) (4) | 02 Nov 2020 21:36:34 |
| DataPoint Un-verified. | (b) (4) Danyel Johnson (b) (4) | 02 Nov 2020 21:34:16 |
| User entered empty; reason for change Data Entry Error | (b) (4) Danyel Johnson (b) (4) | 02 Nov 2020 21:34:16 |
| User opened query 'please delete.' (Site from CRA). | (b) (4), (b) (6) | 29 Oct 2020 01:54:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:27:13 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 04 Aug 2020 15:41:12 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 04 Aug 2020 15:41:12 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:41:12 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 04 Aug 2020 15:40:43 |
| User entered empty. | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:40:43 |

US3832071

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:27:13 |
| User entered empty. | Ashten Sheriff (b) (4) | 04 Aug 2020 15:40:43 |

US3832071

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Dec 2020 21:34:10 |
| User closed query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. ' (Site from CRA). | (b) (4), (b) (6) | 02 Nov 2020 22:05:43 |
| Query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. ' answered with 'UPDATED PER QUERY ' (Site from CRA). | Danyel Johnson (b) (4) (b) (4) | 02 Nov 2020 21:36:38 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 02 Nov 2020 21:35:41 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System | 02 Nov 2020 21:35:41 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Danyel Johnson (b) (4) (b) (4) | 02 Nov 2020 21:35:41 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 02 Nov 2020 21:34:16 |
| DataPoint Un-verified. | Danyel Johnson (b) (4) (b) (4) | 02 Nov 2020 21:34:16 |
| User entered empty; reason for change Data Entry Error | Danyel Johnson (b) (4) (b) (4) | 02 Nov 2020 21:34:16 |
| User opened query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. ' (Site from CRA). | (b) (4), (b) (6) | 29 Oct 2020 01:55:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:27:13 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 04 Aug 2020 15:41:12 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System | 04 Aug 2020 15:41:12 |
| User entered '71' reason for change: Data Entry Error | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:41:12 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 04 Aug 2020 15:40:43 |
| User entered empty. | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:40:43 |

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EAB) (1725)

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'bpm' | System | 02 Nov 2020 21:35:41 |
| User entered empty. | System | 02 Nov 2020 21:34:16 |
| User entered 'bpm' | System | 04 Aug 2020 15:41:12 |
| User entered empty. | System | 04 Aug 2020 15:40:43 |

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Dec 2020 21:34:14 |
| User closed query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. (Site from CRA). | (b) (4), (b) (6) | 02 Nov 2020 22:05:46 |
| Query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. answered with 'UPDATED PER QUERY ' (Site from CRA). | Danyel Johnson (b) (4) (b) (4) | 02 Nov 2020 21:36:50 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 02 Nov 2020 21:35:41 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System | 02 Nov 2020 21:35:41 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Danyel Johnson (b) (4) (b) (4) | 02 Nov 2020 21:35:41 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 02 Nov 2020 21:34:16 |
| DataPoint Un-verified. | Danyel Johnson (b) (4) (b) (4) | 02 Nov 2020 21:34:16 |
| User entered empty; reason for change Data Entry Error | Danyel Johnson (b) (4) (b) (4) | 02 Nov 2020 21:34:16 |
| User opened query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. (Site from CRA). | (b) (4), (b) (6) | 29 Oct 2020 01:55:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:27:13 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 04 Aug 2020 15:41:12 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System | 04 Aug 2020 15:41:12 |
| User entered '17' reason for change: Data Entry Error | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:41:12 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 04 Aug 2020 15:40:43 |
| User entered empty. | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:40:43 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'breaths/min' | System | 02 Nov 2020 21:35:41 |
| User entered empty. | System | 02 Nov 2020 21:34:16 |
| User entered 'breaths/min' | System | 04 Aug 2020 15:41:12 |
| User entered empty. | System | 04 Aug 2020 15:40:43 |

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Dec 2020 21:34:18 |
| User closed query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. ' (Site from CRA). | (b) (4), (b) (6) | 02 Nov 2020 22:06:36 |
| Query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. ' answered with 'UPDATED PER QUERY ' (Site from CRA). | Danyel Johnson (b) (4) (b) (4) | 02 Nov 2020 21:37:14 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 02 Nov 2020 21:35:41 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System | 02 Nov 2020 21:35:41 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Danyel Johnson (b) (4) (b) (4) | 02 Nov 2020 21:35:41 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 02 Nov 2020 21:34:16 |
| DataPoint Un-verified. | Danyel Johnson (b) (4) (b) (4) | 02 Nov 2020 21:34:16 |
| User entered empty; reason for change Data Entry Error | Danyel Johnson (b) (4) (b) (4) | 02 Nov 2020 21:34:16 |
| User opened query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. ' (Site from CRA). | (b) (4), (b) (6) | 29 Oct 2020 01:55:35 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:27:13 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 04 Aug 2020 15:41:12 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System | 04 Aug 2020 15:41:12 |
| User entered '141' reason for change: Data Entry Error | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:41:12 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 04 Aug 2020 15:40:43 |
| User entered empty. | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:40:43 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'mmHg' | System | 02 Nov 2020 21:35:41 |
| User entered empty. | System | 02 Nov 2020 21:34:16 |
| User entered 'mmHg' | System | 04 Aug 2020 15:41:12 |
| User entered empty. | System | 04 Aug 2020 15:40:43 |

US3832071

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Dec 2020 21:34:21 |
| User closed query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. ' (Site from CRA). | (b) (4), (b) (6) | 02 Nov 2020 22:06:39 |
| Query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. ' answered with 'UPDATED PER QUERY ' (Site from CRA). | Danyel Johnson (b) (4) (b) (4) | 02 Nov 2020 21:37:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 02 Nov 2020 21:35:41 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System | 02 Nov 2020 21:35:41 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Danyel Johnson (b) (4) (b) (4) | 02 Nov 2020 21:35:41 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 02 Nov 2020 21:34:16 |
| DataPoint Un-verified. | Danyel Johnson (b) (4) (b) (4) | 02 Nov 2020 21:34:16 |
| User entered empty; reason for change Data Entry Error | Danyel Johnson (b) (4) (b) (4) | 02 Nov 2020 21:34:16 |
| User opened query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. ' (Site from CRA). | (b) (4), (b) (6) | 29 Oct 2020 01:55:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:27:13 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 04 Aug 2020 15:41:12 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System | 04 Aug 2020 15:41:12 |
| User entered '87' reason for change: Data Entry Error | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:41:12 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 04 Aug 2020 15:40:43 |
| User entered empty. | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:40:43 |

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EAB) (1725)

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'mmHg' | System | 02 Nov 2020 21:35:41 |
| User entered empty. | System | 02 Nov 2020 21:34:16 |
| User entered 'mmHg' | System | 04 Aug 2020 15:41:12 |
| User entered empty. | System | 04 Aug 2020 15:40:43 |

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| | | |

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| | | |

US3832071

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:02:20

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:27:30 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:41:24 |

US3832071

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:02:20

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 15:27:30 |
| Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' | (b) (4), (b) (6) | 07 Sep 2020 09:03:54 |
| canceled (Site from System). | | |
| User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System). | | 01 Sep 2020 13:59:56 |
| User entered '04 Aug 2020' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:41:24 |

US3832071

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:02:20

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:38:39 |
| User entered '04 Aug 2020' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:41:45 |

US3832071

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:02:20

[Is the participant of childbearing potential?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:38:39 |
| User entered 'No (N)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:41:45 |

US3832071

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:02:20

If No, what is the reason?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 29 Oct 2020 09:48:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Oct 2020 01:43:56 |
| Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'Verified and updated' (Site from DM). | Alyssa-Kay Peay (b) (4) (b) (4) | 20 Oct 2020 19:10:25 |
| DataPoint Un-verified. | Alyssa-Kay Peay (b) (4) (b) (4) | 20 Oct 2020 19:08:33 |
| User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error | Alyssa-Kay Peay (b) (4) (b) (4) | 20 Oct 2020 19:08:33 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:38:39 |
| User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 30 Sep 2020 07:01:13 |
| User entered 'Post-menopausal (POST-MENOPAUSAL)' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:41:45 |

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:02:20

[If Partner medically sterile or Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:38:39 |
| User entered empty. | Ashten Sheriff (b) (4) | 04 Aug 2020 15:41:45 |

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:02:20

If Surgically sterile, date of surgery (dd MMM yyyy)

| Audit | User | Time (GMT) |
|-----------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 29 Oct 2020 01:59:28 |
| DataPoint Un-verified. | Alyssa-Kay Peay (b) (4) | 20 Oct 2020 19:08:33 |
| User entered 'UN UNK 1982' reason for change: | (b) (4) | |
| Data Entry Error | Alyssa-Kay Peay (b) (4) | 20 Oct 2020 19:08:33 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 14 Oct 2020 15:38:39 |
| User entered empty. | Ashten Sheriff (b) (4) | 04 Aug 2020 15:41:45 |
| | (b) (4) | |

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:02:20

[Date of surgery unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:38:39 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:41:45 |

US3832071

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:02:20

If Post-menopausal, date of last menstruation (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:38:39 |
| User entered empty. | Ashten Sheriff (b) (4) | 04 Aug 2020 15:41:45 |

US3832071

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:02:20

Date of last menstruation unknown

| Audit | User | Time (GMT) |
|------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 29 Oct 2020 01:44:08 |
| DataPoint Un-verified. | Alyssa-Kay Peay (b) (4) | 20 Oct 2020 19:08:33 |
| User entered '0' reason for change: Data Entry Error | (b) (4) Alyssa-Kay Peay (b) (4) | 20 Oct 2020 19:08:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 15:38:39 |
| User entered '1' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:41:45 |

US3832071

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:20

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) | 15 Dec 2020 20:29:47 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 15 Dec 2020 20:29:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:44:58 |
| User entered 'No (N)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:43:18 |
| | (b) (4) | |

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:20

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 15:44:58 |
| User entered 'No (N)' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:43:18 |

US3832071

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:20

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) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 15:44:58 |
| User entered 'No (N)' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:43:18 |

US3832071

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:20

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) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:44:58 |
| User entered 'No (N)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:43:18 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:20

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 15:44:58 |
| User entered 'No (N)' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:43:18 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:20

[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) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:44:58 |
| User entered 'No (N)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:43:18 |

US3832071

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:20

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) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:44:58 |
| User entered 'No (N)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:43:18 |

US3832071

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:20

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) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:44:58 |
| User entered 'No (N)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:43:18 |

US3832071

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:20

[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) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 15:44:58 |
| User entered 'No (N)' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:43:18 |

US3832071

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:20

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) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 15:44:58 |
| User entered 'No (N)' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:43:18 |

US3832071

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:20

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) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:44:58 |
| User entered 'No (N)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:43:18 |

US3832071

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:20

Other

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Dec 2020 19:54:28 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 07 Dec 2020 15:03:24 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 07 Dec 2020 15:03:24 |
| User entered 'No (N)' reason for change: Data Entry Error | Danyel Johnson (b) (4) (b) (4) | 07 Dec 2020 15:03:24 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 07 Dec 2020 15:03:18 |
| User entered empty; reason for change Data Entry Error | Danyel Johnson (b) (4) (b) (4) | 07 Dec 2020 15:03:18 |
| DataPoint Un-verified. | Danyel Johnson (b) (4) (b) (4) | 07 Dec 2020 15:03:02 |
| User entered 'No (N)' reason for change: Data Entry Error | Danyel Johnson (b) (4) (b) (4) | 07 Dec 2020 15:03:02 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:44:58 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:43:18 |

US3832071

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:20

[Specify](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Dec 2020 19:54:31 |
| DataPoint Un-verified. | Danyel Johnson (b) (4) | 07 Dec 2020 15:03:02 |
| User entered empty; reason for change Data Entry Error | (b) (4) Danyel Johnson (b) (4) | 07 Dec 2020 15:03:02 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:44:58 |
| User entered 'participant plan on routinely (e.g., weekly) going to places where people gather (e.g., places of worship, restaurants, bars, sporting events) over the coming months' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:43:18 |

US3832071

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:20

No Risk Identified

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| User closed query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System). | (b) (4) | |
| User entered '0' reason for change: Data Entry Error | System | 09 Dec 2020 17:44:08 |
| User closed query 'please tick living condition. If none of the selections are applicable, select 'other' and specify (ie homeless)' (Site from CRA). | Danyel Johnson (b) (4) | 09 Dec 2020 17:44:08 |
| Query 'please tick living condition. If none of the selections are applicable, select 'other' and specify (ie homeless)' answered with 'updated' (Site from CRA). | (b) (4) | |
| User opened query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System). | (b) (4), (b) (6) | 08 Dec 2020 19:53:39 |
| User opened query 'please tick living condition. If none of the selections are applicable, select 'other' and specify (ie homeless)' (Site from CRA). | Danyel Johnson (b) (4) | 07 Dec 2020 15:02:37 |
| User closed query 'please tick living condition. If none of the selections are applicable, select 'other' and specify (ie homeless)' (Site from CRA). | (b) (4) | |
| User entered '1' reason for change: Data Entry Error | System | 07 Dec 2020 15:02:30 |
| User opened query 'please tick living condition. If none of the selections are applicable, select 'other' and specify (ie homeless)' (Site from CRA). | (b) (4), (b) (6) | 03 Dec 2020 21:35:41 |
| User closed query 'please tick living condition. If none of the selections are applicable, select 'other' and specify (ie homeless)' (Site from CRA). | (b) (4), (b) (6) | 02 Nov 2020 22:07:50 |
| Query 'please tick living condition. If none of the selections are applicable, select 'other' and specify (ie homeless)' answered with 'updated' (Site from CRA). | Danyel Johnson (b) (4) | 02 Nov 2020 21:33:17 |
| User entered '1' reason for change: Data Entry Error | (b) (4) | |
| User opened query 'please tick living condition. If none of the selections are applicable, select 'other' and specify (ie homeless)' (Site from CRA). | (b) (4), (b) (6) | 02 Nov 2020 21:32:45 |
| User entered '0' | (b) (4) | |
| | (b) (4), (b) (6) | 29 Oct 2020 01:53:30 |
| | Ashten Sheriff (b) (4) | 04 Aug 2020 15:43:18 |
| | (b) (4) | |

US3832071

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:20

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:44:58 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:43:18 |

US3832071

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:20

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) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:44:58 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:43:18 |

US3832071

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:20

[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) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 15:44:58 |
| User entered '0' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:43:18 |

US3832071

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:20

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) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:44:58 |
| User entered '0' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:43:18 |

US3832071

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:20

[Resides in a single family home](#) (i.e., detached housing)

| Audit | User | Time (GMT) |
|------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Dec 2020 19:53:42 |
| User entered '1' reason for change: Data Entry Error | Danyel Johnson (b) (4) | 07 Dec 2020 15:02:30 |
| DataPoint Un-verified. | (b) (4) (b) (4), (b) (6) | 03 Dec 2020 21:44:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:44:58 |
| User entered '0' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:43:18 |

US3832071

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:20

[Other](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| User closed query 'This section is for living conditions. please delete this.' (Site from CRA). | (b) (4) | |
| Query 'This section is for living conditions. please delete this.' answered with 'Updated' (Site from CRA). | (b) (4), (b) (6) | 02 Nov 2020 22:08:36 |
| | Danyel Johnson (b) (4) | 02 Nov 2020 21:33:23 |
| User entered '0' reason for change: Data Entry Error | (b) (4) | 02 Nov 2020 21:32:45 |
| User opened query 'This section is for living conditions. please delete this.' (Site from CRA). | (b) (4), (b) (6) | 29 Oct 2020 01:47:25 |
| User entered '1' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:43:18 |
| | (b) (4) | |

US3832071

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:20

[Specify](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Dec 2020 21:35:55 |
| User closed query 'This section is for living conditions. please delete this.' (Site from CRA). | (b) (4), (b) (6) | 02 Nov 2020 22:08:39 |
| Query 'This section is for living conditions. please delete this.' answered with 'UPdated' (Site from CRA). | Danyel Johnson (b) (4) | 02 Nov 2020 21:33:30 |
| DataPoint Un-verified. | Danyel Johnson (b) (4) | 02 Nov 2020 21:32:45 |
| User entered empty; reason for change Data Entry Error | Danyel Johnson (b) (4) | 02 Nov 2020 21:32:45 |
| User opened query 'This section is for living conditions. please delete this.' (Site from CRA). | (b) (4), (b) (6) | 29 Oct 2020 01:47:33 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:44:58 |
| User entered 'participant plan on routinely (e.g., weekly) going to places where people gather (e.g., places of worship, restaurants, bars, sporting events) over the coming months' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:43:18 |

US3832071

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:02:20

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:59:24 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:45:22 |

US3832071

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:59:24 |
| User entered '04 Aug 2020' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:45:22 |

US3832071

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 15:59:24 |
| User entered 'Clinic (Clinic)' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:45:22 |

US3832071

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:02:20

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'VISIT1' | System | 04 Aug 2020 15:45:22 |

US3832071

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 15:59:56 |
| User entered '04 AUG 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 04 Aug 2020 15:14:48 |

US3832071

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:02:20

What was the participant's randomization number?

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 15:59:56 |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 21 Aug 2020 01:55:25 |
| Amendment Manager: Data point set to conformant. | System | 21 Aug 2020 01:55:25 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 04 Aug 2020 15:14:48 |
| User entered '142841' (non-conformant). | RWS_ENDPOINT ENDPOINT (b) (4) | 04 Aug 2020 15:14:48 |

US3832071

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:02:20

[In what Cohort was the participant enrolled?](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 15:59:56 |
| User entered '>=18 and <65 years and at risk (2)' | RWS_ENDPOINT ENDPOINT (b) (4) | 04 Aug 2020 15:14:48 |

US3832071

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:02:20

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) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:59:56 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) | 04 Aug 2020 21:44:48 |

US3832071

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:02:20

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) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:59:56 |
| User entered 'No (N)' | Ashten Sheriff (b) (4) | 04 Aug 2020 21:44:48 |

US3832071

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:02:20

Severe obesity (body mass index > or = 40kg/m2)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:59:56 |
| User entered 'No (N)' | Ashten Sheriff (b) (4) | 04 Aug 2020 21:44:48 |

US3832071

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:02:20

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:59:56 |
| User entered 'No (N)' | Ashten Sheriff (b) (4) | 04 Aug 2020 21:44:48 |

US3832071

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:02:20

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:59:56 |
| User entered 'No (N)' | Ashten Sheriff (b) (4) | 04 Aug 2020 21:44:48 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:02:20

Height

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Nov 2020 21:10:29 |
| User closed query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 0. (Site from CRA). | (b) (4), (b) (6) | 02 Nov 2020 21:10:25 |
| Query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 0. answered with 'Verified and updated' (Site from CRA). | Alyssa-Kay Peay (b) (4) | 29 Oct 2020 13:03:49 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 29 Oct 2020 13:03:38 |
| DataPoint Un-verified. | Alyssa-Kay Peay (b) (4) | 29 Oct 2020 13:03:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 29 Oct 2020 13:03:27 |
| User opened query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 0. (Site from CRA). | (b) (4), (b) (6) | 29 Oct 2020 01:56:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| User entered '172' cm | Ashten Sheriff (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:02:20

Weight

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Nov 2020 21:10:36 |
| User closed query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 0. (Site from CRA). | (b) (4), (b) (6) | 02 Nov 2020 21:10:34 |
| Query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 0. answered with 'Verified and updated' (Site from CRA). | Alyssa-Kay Peay (b) (4) | 29 Oct 2020 13:03:56 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 29 Oct 2020 13:03:38 |
| DataPoint Un-verified. | Alyssa-Kay Peay (b) (4) | 29 Oct 2020 13:03:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 29 Oct 2020 13:03:27 |
| User opened query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 0. (Site from CRA). | (b) (4), (b) (6) | 29 Oct 2020 01:56:20 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| User entered '84.2' kg | Ashten Sheriff (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:02:20

Height

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Nov 2020 21:10:29 |
| User closed query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 0. (Site from CRA). | (b) (4), (b) (6) | 02 Nov 2020 21:10:25 |
| Query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 0. answered with 'Verified and updated' (Site from CRA). | Alyssa-Kay Peay (b) (4) | 29 Oct 2020 13:03:49 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 29 Oct 2020 13:03:38 |
| DataPoint Un-verified. | Alyssa-Kay Peay (b) (4) | 29 Oct 2020 13:03:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 29 Oct 2020 13:03:27 |
| User opened query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 0. (Site from CRA). | (b) (4), (b) (6) | 29 Oct 2020 01:56:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| User entered '172' cm | Ashten Sheriff (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:02:20

Weight

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Nov 2020 21:10:36 |
| User closed query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 0. ' (Site from CRA). | (b) (4), (b) (6) | 02 Nov 2020 21:10:34 |
| Query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 0. ' answered with 'Verified and updated' (Site from CRA). | Alyssa-Kay Peay (b) (4) (b) (4) | 29 Oct 2020 13:03:56 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Alyssa-Kay Peay (b) (4) (b) (4) | 29 Oct 2020 13:03:38 |
| DataPoint Un-verified. | Alyssa-Kay Peay (b) (4) (b) (4) | 29 Oct 2020 13:03:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Alyssa-Kay Peay (b) (4) (b) (4) | 29 Oct 2020 13:03:27 |
| User opened query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 0. ' (Site from CRA). | (b) (4), (b) (6) | 29 Oct 2020 01:56:20 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| User entered '84.2' kg | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

[Timepoint](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| User entered '04 Aug 2020' | Ashten Sheriff (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| User entered '10:52' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered '04 Aug 2020 10:52' | System | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| User entered '97.7' F | Ashten Sheriff (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| User entered 'Oral (Oral)' | Ashten Sheriff (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| User entered empty. | Ashten Sheriff (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| User entered '71' | Ashten Sheriff (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'bpm' | System | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| User entered '17' | Ashten Sheriff (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'breaths/min' | System | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| User entered '141' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'mmHg' | System | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| User entered '87' | Ashten Sheriff (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'mmHg' | System | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:02:20

Height

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Nov 2020 21:10:29 |
| User closed query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 0. (Site from CRA). | (b) (4), (b) (6) | 02 Nov 2020 21:10:25 |
| Query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 0. answered with 'Verified and updated' (Site from CRA). | Alyssa-Kay Peay (b) (4) | 29 Oct 2020 13:03:49 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 29 Oct 2020 13:03:38 |
| DataPoint Un-verified. | Alyssa-Kay Peay (b) (4) | 29 Oct 2020 13:03:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 29 Oct 2020 13:03:27 |
| User opened query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 0. (Site from CRA). | (b) (4), (b) (6) | 29 Oct 2020 01:56:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| User entered '172' cm | Ashten Sheriff (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:02:20

Weight

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Nov 2020 21:10:36 |
| User closed query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 0. (Site from CRA). | (b) (4), (b) (6) | 02 Nov 2020 21:10:34 |
| Query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 0. answered with 'Verified and updated' (Site from CRA). | Alyssa-Kay Peay (b) (4) | 29 Oct 2020 13:03:56 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 29 Oct 2020 13:03:38 |
| DataPoint Un-verified. | Alyssa-Kay Peay (b) (4) | 29 Oct 2020 13:03:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 29 Oct 2020 13:03:27 |
| User opened query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 0. (Site from CRA). | (b) (4), (b) (6) | 29 Oct 2020 01:56:20 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| User entered '84.2' kg | Ashten Sheriff (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

[Timepoint](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| User entered '04 Aug 2020' | Ashten Sheriff (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 18 Aug 2020 13:04:52 |
| User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System). | | 04 Aug 2020 21:46:56 |
| User entered '12:06' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered '04 Aug 2020 12:06' | System | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| User entered '97.2' F | Ashten Sheriff (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| User entered 'Oral (Oral)' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| User entered empty. | Ashten Sheriff (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| User entered '73' | Ashten Sheriff (b) (4) | 04 Aug 2020 21:46:56 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'bpm' | System | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| User entered '16' | Ashten Sheriff (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'breaths/min' | System | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| Amendment Manager: User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | System | 16 Sep 2020 23:42:16 |
| Amendment Manager: Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System). | System | 16 Sep 2020 23:42:16 |
| Amendment Manager: Query text changed to "Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate." | System | 16 Sep 2020 23:42:15 |
| User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | System | 04 Aug 2020 21:46:56 |
| User entered '156' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 21:46:56 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'mmHg' | System | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:02:19 |
| User entered '86' | Ashten Sheriff (b) (4) | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'mmHg' | System | 04 Aug 2020 21:46:56 |

US3832071

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:02:20

Was the physical examination performed?

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Dec 2020 21:36:59 |
| User closed query 'Per query response, ND. Please enter N0 into the database. ' (Site from CRA). | (b) (4), (b) (6) | 10 Nov 2020 20:00:47 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 10 Nov 2020 13:04:18 |
| Query 'Per query response, ND. Please enter N0 into the database. ' answered with 'updated ' (Site from CRA). | Alyssa-Kay Peay (b) (4) (b) (4) | 09 Nov 2020 16:33:10 |
| User entered 'No (N)' reason for change: Data Entry Error | Alyssa-Kay Peay (b) (4) (b) (4) | 09 Nov 2020 16:32:56 |
| User opened query 'Per query response, ND. Please enter N0 into the database. ' (Site from CRA). | (b) (4), (b) (6) | 08 Nov 2020 22:13:16 |
| User closed query 'Per EDC guidelines, NO must be recorded if Day 0 and Day 1 are performed on the same date, this is only entered on Day . Please verify and reconcile ' (Site from CRA). | (b) (4), (b) (6) | 08 Nov 2020 22:13:16 |
| Query 'Per EDC guidelines, NO must be recorded if Day 0 and Day 1 are performed on the same date, this is only entered on Day . Please verify and reconcile ' answered with 'ND' (Site from CRA). | Alyssa-Kay Peay (b) (4) (b) (4) | 05 Nov 2020 18:35:51 |
| User opened query 'Per EDC guidelines, NO must be recorded if Day 0 and Day 1 are performed on the same date, this is only entered on Day . Please verify and reconcile ' (Site from CRA). | (b) (4), (b) (6) | 05 Nov 2020 17:06:45 |
| User closed query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 0. ' (Site from CRA). | (b) (4), (b) (6) | 05 Nov 2020 17:06:45 |
| Query 'Data is required. Please complete.' answered with 'PATIENT COMPLETED VISIT 0 AND DAY 1 ON THE SAME DAY. ND ' (Site from System). | Danyel Johnson (b) (4) (b) (4) | 02 Nov 2020 21:47:42 |

US3832071

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:02:20

Was the physical examination performed?

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 0. ' answered with 'PATIENT COMPLETED VISIT 0 AND DAY 1 ON THE SAME DAY. ND ' (Site from CRA). | Danyel Johnson (b) (4) | 02 Nov 2020 21:47:37 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 02 Nov 2020 21:46:13 |
| DataPoint Un-verified. | Danyel Johnson (b) (4) | 02 Nov 2020 21:46:13 |
| User entered empty; reason for change Data Entry Error | Danyel Johnson (b) (4) | 02 Nov 2020 21:46:13 |
| User opened query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 0. ' (Site from CRA). | (b) (4), (b) (6) | 29 Oct 2020 01:56:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:02:42 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) | 04 Aug 2020 21:47:09 |

US3832071

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:02:20

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Dec 2020 21:37:06 |
| User closed query 'please delete' (Site from CRA). | (b) (4), (b) (6) | 05 Nov 2020 17:07:00 |
| Query 'please delete' answered with 'PATIENT COMPLETED VISIT 0 AND DAY 1 ON THE SAME DAY. ND ' (Site from CRA). | Danyel Johnson (b) (4) | 02 Nov 2020 21:47:45 |
| DataPoint Un-verified. | Danyel Johnson (b) (4) | 02 Nov 2020 21:46:13 |
| User entered empty; reason for change Data Entry Error | Danyel Johnson (b) (4) | 02 Nov 2020 21:46:13 |
| User opened query 'please delete' (Site from CRA). | (b) (4), (b) (6) | 29 Oct 2020 01:56:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:02:42 |
| User entered '04 Aug 2020' | Ashten Sheriff (b) (4) | 04 Aug 2020 21:47:09 |

US3832071

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:02:20

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:03:20 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:45:45 |

US3832071

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:02:20

If No, reason not given

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:03:20 |
| User entered empty. | Ashten Sheriff (b) (4) | 04 Aug 2020 15:45:45 |

US3832071

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:02:20

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) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:03:20 |
| User entered empty. | Ashten Sheriff (b) (4) | 04 Aug 2020 15:45:45 |

US3832071

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:02:20

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:02:20

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:03:20 |
| User entered '04 Aug 2020' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:45:45 |

US3832071

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:02:20

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:03:20 |
| User entered '11:34' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 15:45:45 |

US3832071

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:02:20

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered '04 Aug 2020 11:34' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:02:20

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:03:20 |
| User entered 'Left Arm (LEFT ARM)' | Ashten Sheriff (b) (4) | 04 Aug 2020 15:45:45 |

US3832071

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:02:20

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:03:20 |
| User entered 'ONCE' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:02:20

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'INTRAMUSCULAR' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:20

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:03:30 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) | 04 Aug 2020 21:47:29 |

US3832071

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:20

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:03:30 |
| User entered '04 Aug 2020' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 21:47:29 |

US3832071

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:20

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:03:30 |
| User entered '11:33' | Ashten Sheriff (b) (4) | 04 Aug 2020 21:47:29 |

US3832071

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:20

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered '04 Aug 2020 11:33' | System | 04 Aug 2020 21:47:29 |

US3832071

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:02:20

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| User closed query 'Per source, sample collected time doesn't match. Please verify and reconcile. ' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 26 Oct 2020 17:04:38 |
| Query 'Per source, sample collected time doesn't match. Please verify and reconcile. ' answered with 'confirmed in CRIO' (Site from CRA). | Emma Partin (b) (4) (b) (4) | 20 Oct 2020 19:49:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:05:05 |
| User opened query 'Per source, sample collected time doesn't match. Please verify and reconcile. ' (Site from CRA). | (b) (4), (b) (6) | 14 Oct 2020 16:05:00 |
| User entered '04 Aug 2020' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 21:47:49 |

US3832071

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:02:20

[Lab Test](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 21:47:49 |

US3832071

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:02:20

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Oct 2020 01:57:57 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) | 04 Aug 2020 21:47:49 |

US3832071

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:02:20

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Oct 2020 01:58:26 |
| User entered '11:22' | Ashten Sheriff (b) (4) | 04 Aug 2020 21:47:49 |

US3832071

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:02:20

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered '04 Aug 2020 11:22' | System | 04 Aug 2020 21:47:49 |

US3832071

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:02:20

[Lab Test](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Ashten Sheriff (b) (4) (b) (4) | 04 Aug 2020 21:47:49 |

US3832071

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:02:20

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Dec 2020 21:36:35 |
| User entered 'No (N)' reason for change: Data Entry Error | Alyssa-Kay Peay (b) (4) | 10 Nov 2020 22:01:36 |
| User closed query 'please confirm if 2nd swab was collected. If not, enter ND. ' (Site from CRA). | (b) (4), (b) (6) | 10 Nov 2020 21:36:29 |
| Query 'please confirm if 2nd swab was collected. If not, enter ND. ' answered with 'CONFIRMED PER SOURCE' (Site from CRA). | Danyel Johnson (b) (4) | 02 Nov 2020 21:39:30 |
| User opened query 'please confirm if 2nd swab was collected. If not, enter ND. ' (Site from CRA). | (b) (4), (b) (6) | 29 Oct 2020 01:57:29 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) | 04 Aug 2020 21:47:49 |

US3832071

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:02:20

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Dec 2020 21:36:33 |
| User entered empty; reason for change Data Entry Error | Alyssa-Kay Peay (b) (4) | 10 Nov 2020 22:01:36 |
| User closed query 'if 2nd swab was not collected, delete this entry. ' (Site from CRA). | (b) (4), (b) (6) | 10 Nov 2020 21:36:32 |
| Query 'if 2nd swab was not collected, delete this entry. ' answered with 'CONFIRMED PER SOURCE' (Site from CRA). | Danyel Johnson (b) (4) | 02 Nov 2020 21:39:35 |
| User opened query 'if 2nd swab was not collected, delete this entry. ' (Site from CRA). | (b) (4), (b) (6) | 29 Oct 2020 01:57:49 |
| User entered '11:22' | Ashten Sheriff (b) (4) | 04 Aug 2020 21:47:49 |

US3832071

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:02:20

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered empty. | System | 10 Nov 2020 22:01:36 |
| User entered '04 Aug 2020 11:22' | System | 04 Aug 2020 21:47:49 |

US3832071

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:17:05 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) | 04 Aug 2020 21:47:56 |

US3832071

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'I' | System | 04 Aug 2020 21:47:56 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T12:07:49', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '2f788742-ee1b-48a2-91e6-9703449bb1b8' | System | 04 Aug 2020 16:06:29 |
| User entered 'Yes (Y)' | System | 04 Aug 2020 16:06:29 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T12:08:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '2f788742-ee1b-48a2-91e6-9703449bb1b8' | System | 04 Aug 2020 16:06:29 |
| User entered '97.2' | System | 04 Aug 2020 16:06:29 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T12:08:06', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '2f788742-ee1b-48a2-91e6-9703449bb1b8' | System | 04 Aug 2020 16:06:29 |
| User entered 'No (N)' | System | 04 Aug 2020 16:06:29 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T12:08:23', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '2f788742-ee1b-48a2-91e6-9703449bb1b8' | System | 04 Aug 2020 16:06:29 |
| User entered '04 Aug 2020 12:08' | System | 04 Aug 2020 16:06:29 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '04 Aug 2020 11:54' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '04 Aug 2020 14:24' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 1, after vaccination (at home)' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T22:41:15', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '2c523799-e5ce-4b8a-80d0-a1af83ea22e8' | System | 05 Aug 2020 02:39:54 |
| User entered 'Yes (Y)' | System | 05 Aug 2020 02:39:54 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T22:41:25', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '2c523799-e5ce-4b8a-80d0-a1af83ea22e8' | System | 05 Aug 2020 02:39:54 |
| User entered '95.9' | System | 05 Aug 2020 02:39:54 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T22:41:31', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '2c523799-e5ce-4b8a-80d0-a1af83ea22e8' | System | 05 Aug 2020 02:39:54 |
| User entered 'No (N)' | System | 05 Aug 2020 02:39:54 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T22:41:49', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '2c523799-e5ce-4b8a-80d0-a1af83ea22e8' | System | 05 Aug 2020 02:39:54 |
| User entered '04 Aug 2020 22:41' | System | 05 Aug 2020 02:39:54 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '04 Aug 2020 15:19' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '05 Aug 2020 11:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 2' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:02:20

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-05T17:21:25', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '4d658c3d-9323-4ec6-bcbc-53f2d4026a07' | System | 05 Aug 2020 21:20:15 |
| User entered 'Yes (Y)' | System | 05 Aug 2020 21:20:15 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:02:20

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-05T17:21:34', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '4d658c3d-9323-4ec6-bcbc-53f2d4026a07' | System | 05 Aug 2020 21:20:15 |
| User entered '98.1' | System | 05 Aug 2020 21:20:15 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-05T17:22:02', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '4d658c3d-9323-4ec6-bcbc-53f2d4026a07' | System | 05 Aug 2020 21:20:15 |
| User entered 'No (N)' | System | 05 Aug 2020 21:20:15 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-05T17:22:10', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '4d658c3d-9323-4ec6-bcbc-53f2d4026a07' | System | 05 Aug 2020 21:20:15 |
| User entered '05 Aug 2020 17:22' | System | 05 Aug 2020 21:20:15 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '05 Aug 2020 12:00' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '06 Aug 2020 11:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 3' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:02:20

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-06T22:00:18', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'd166f6df-dbcd-4853-b90d-3825d6a435d8' | System | 07 Aug 2020 01:58:35 |
| User entered 'Yes (Y)' | System | 07 Aug 2020 01:58:35 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:02:20

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-06T22:00:23', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'd166f6df-dbcd-4853-b90d-3825d6a435d8' | System | 07 Aug 2020 01:58:35 |
| User entered '97.1' | System | 07 Aug 2020 01:58:35 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-06T22:00:28', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'd166f6df-dbcd-4853-b90d-3825d6a435d8' | System | 07 Aug 2020 01:58:35 |
| User entered 'No (N)' | System | 07 Aug 2020 01:58:35 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-06T22:00:33', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'd166f6df-dbcd-4853-b90d-3825d6a435d8' | System | 07 Aug 2020 01:58:35 |
| User entered '06 Aug 2020 22:00' | System | 07 Aug 2020 01:58:35 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '06 Aug 2020 12:00' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '07 Aug 2020 11:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 4' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:02:20

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-07T22:18:42', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '0d310a41-3db2-4d66-a285-6b7dbaf883dd' | System | 08 Aug 2020 02:17:04 |
| User entered 'Yes (Y)' | System | 08 Aug 2020 02:17:04 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:02:20

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-07T22:18:48', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '0d310a41-3db2-4d66-a285-6b7dbaf883dd' | System | 08 Aug 2020 02:17:04 |
| User entered '96.7' | System | 08 Aug 2020 02:17:04 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-07T22:18:54', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '0d310a41-3db2-4d66-a285-6b7dbaf883dd' | System | 08 Aug 2020 02:17:04 |
| User entered 'No (N)' | System | 08 Aug 2020 02:17:04 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-07T22:19:02', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '0d310a41-3db2-4d66-a285-6b7dbaf883dd' | System | 08 Aug 2020 02:17:04 |
| User entered '07 Aug 2020 22:19' | System | 08 Aug 2020 02:17:04 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '07 Aug 2020 12:00' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '08 Aug 2020 11:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 5' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:02:20

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-08T23:03:38', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'c9057f77-51bd-4e0a-becd-09f40215f707' | System | 09 Aug 2020 03:01:55 |
| User entered 'Yes (Y)' | System | 09 Aug 2020 03:01:55 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:02:20

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-08T23:03:45', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'c9057f77-51bd-4e0a-becd-09f40215f707' | System | 09 Aug 2020 03:01:55 |
| User entered '97.9' | System | 09 Aug 2020 03:01:55 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-08T23:03:50', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'c9057f77-51bd-4e0a-becd-09f40215f707' | System | 09 Aug 2020 03:01:55 |
| User entered 'No (N)' | System | 09 Aug 2020 03:01:55 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-08T23:03:56', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'c9057f77-51bd-4e0a-becd-09f40215f707' | System | 09 Aug 2020 03:01:55 |
| User entered '08 Aug 2020 23:03' | System | 09 Aug 2020 03:01:55 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '08 Aug 2020 12:00' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '09 Aug 2020 11:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 6' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:02:20

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| | | |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:02:20

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| | | |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| | | |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| | | |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:02:20

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| | | |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| | | |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '09 Aug 2020 12:00' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '10 Aug 2020 11:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 7' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:02:20

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-10T22:33:16', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'c69f62ce-198d-4aff-b33d-45e3f52ab64d' | System | 11 Aug 2020 02:31:26 |
| User entered 'Yes (Y)' | System | 11 Aug 2020 02:31:26 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:02:20

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-10T22:33:22', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'c69f62ce-198d-4aff-b33d-45e3f52ab64d' | System | 11 Aug 2020 02:31:26 |
| User entered '97.6' | System | 11 Aug 2020 02:31:26 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-10T22:33:25', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'c69f62ce-198d-4aff-b33d-45e3f52ab64d' | System | 11 Aug 2020 02:31:26 |
| User entered 'No (N)' | System | 11 Aug 2020 02:31:26 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-10T22:33:31', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'c69f62ce-198d-4aff-b33d-45e3f52ab64d' | System | 11 Aug 2020 02:31:26 |
| User entered '10 Aug 2020 22:33' | System | 11 Aug 2020 02:31:26 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '10 Aug 2020 12:00' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '11 Aug 2020 11:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T12:08:34', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '6cef0089-68ae-4e16-ad1c-4954dacdf173' | System | 04 Aug 2020 16:07:11 |
| User entered 'None (1)' | System | 04 Aug 2020 16:07:11 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T12:08:44', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '6cef0089-68ae-4e16-ad1c-4954dacdf173' | System | 04 Aug 2020 16:07:11 |
| User entered 'No (N)' | System | 04 Aug 2020 16:07:11 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T12:08:48', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '6cef0089-68ae-4e16-ad1c-4954dacdf173' | System | 04 Aug 2020 16:07:11 |
| User entered 'No (N)' | System | 04 Aug 2020 16:07:11 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T12:08:55', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '6cef0089-68ae-4e16-ad1c-4954dacdf173' | System | 04 Aug 2020 16:07:11 |
| User entered 'None (1)' | System | 04 Aug 2020 16:07:11 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T12:09:04', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '6cef0089-68ae-4e16-ad1c-4954dacdf173' | System | 04 Aug 2020 16:07:11 |
| User entered '04 Aug 2020 12:09' | System | 04 Aug 2020 16:07:11 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '04 Aug 2020 11:54' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '04 Aug 2020 14:24' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 1, after vaccination (at home)' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T22:42:07', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '4419aecf-2ed7-4d93-b9b8-be8d9594a2ee' | System | 05 Aug 2020 02:41:13 |
| User entered 'None (1)' | System | 05 Aug 2020 02:41:13 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T22:42:28', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '4419aecf-2ed7-4d93-b9b8-be8d9594a2ee' | System | 05 Aug 2020 02:41:13 |
| User entered 'No (N)' | System | 05 Aug 2020 02:41:13 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T22:42:46', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '4419aecf-2ed7-4d93-b9b8-be8d9594a2ee' | System | 05 Aug 2020 02:41:13 |
| User entered 'No (N)' | System | 05 Aug 2020 02:41:13 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T22:42:52', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '4419aecf-2ed7-4d93-b9b8-be8d9594a2ee' | System | 05 Aug 2020 02:41:13 |
| User entered 'None (1)' | System | 05 Aug 2020 02:41:13 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T22:43:07', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '4419aecf-2ed7-4d93-b9b8-be8d9594a2ee' | System | 05 Aug 2020 02:41:13 |
| User entered '04 Aug 2020 22:43' | System | 05 Aug 2020 02:41:13 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '04 Aug 2020 15:19' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '05 Aug 2020 11:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 2' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-05T17:22:31', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '11f0a9db-2f6c-4c89-bc52-24dd5f614a9b' | System | 05 Aug 2020 21:21:22 |
| User entered 'Does not interfere with activity (2)' | System | 05 Aug 2020 21:21:22 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-05T17:22:44', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '11f0a9db-2f6c-4c89-bc52-24dd5f614a9b' | System | 05 Aug 2020 21:21:22 |
| User entered 'No (N)' | System | 05 Aug 2020 21:21:22 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-05T17:22:51', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '11f0a9db-2f6c-4c89-bc52-24dd5f614a9b' | System | 05 Aug 2020 21:21:22 |
| User entered 'No (N)' | System | 05 Aug 2020 21:21:22 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-05T17:22:56', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '11f0a9db-2f6c-4c89-bc52-24dd5f614a9b' | System | 05 Aug 2020 21:21:22 |
| User entered 'None (1)' | System | 05 Aug 2020 21:21:22 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-05T17:23:17', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '11f0a9db-2f6c-4c89-bc52-24dd5f614a9b' | System | 05 Aug 2020 21:21:22 |
| User entered '05 Aug 2020 17:23' | System | 05 Aug 2020 21:21:22 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '05 Aug 2020 12:00' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '06 Aug 2020 11:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 3' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-06T22:00:45', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '949e14a1-3b97-4f3f-ae87-d62d62e065aa' | System | 07 Aug 2020 01:59:07 |
| User entered 'None (1)' | System | 07 Aug 2020 01:59:07 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-06T22:00:49', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '949e14a1-3b97-4f3f-ae87-d62d62e065aa' | System | 07 Aug 2020 01:59:07 |
| User entered 'No (N)' | System | 07 Aug 2020 01:59:07 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-06T22:00:52', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '949e14a1-3b97-4f3f-ae87-d62d62e065aa' | System | 07 Aug 2020 01:59:07 |
| User entered 'No (N)' | System | 07 Aug 2020 01:59:07 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-06T22:01:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '949e14a1-3b97-4f3f-ae87-d62d62e065aa' | System | 07 Aug 2020 01:59:07 |
| User entered 'None (1)' | System | 07 Aug 2020 01:59:07 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-06T22:01:05', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '949e14a1-3b97-4f3f-ae87-d62d62e065aa' | System | 07 Aug 2020 01:59:07 |
| User entered '06 Aug 2020 22:01' | System | 07 Aug 2020 01:59:07 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '06 Aug 2020 12:00' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '07 Aug 2020 11:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 4' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-07T22:19:07', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'e5298a28-8c9a-414f-b928-21bc495795bf' | System | 08 Aug 2020 02:17:21 |
| User entered 'None (1)' | System | 08 Aug 2020 02:17:21 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-07T22:19:10', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'e5298a28-8c9a-414f-b928-21bc495795bf' | System | 08 Aug 2020 02:17:21 |
| User entered 'No (N)' | System | 08 Aug 2020 02:17:21 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-07T22:19:13', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'e5298a28-8c9a-414f-b928-21bc495795bf' | System | 08 Aug 2020 02:17:21 |
| User entered 'No (N)' | System | 08 Aug 2020 02:17:21 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-07T22:19:16', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'e5298a28-8c9a-414f-b928-21bc495795bf' | System | 08 Aug 2020 02:17:21 |
| User entered 'None (1)' | System | 08 Aug 2020 02:17:21 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-07T22:19:22', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'e5298a28-8c9a-414f-b928-21bc495795bf' | System | 08 Aug 2020 02:17:21 |
| User entered '07 Aug 2020 22:19' | System | 08 Aug 2020 02:17:21 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '07 Aug 2020 12:00' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '08 Aug 2020 11:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 5' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-08T23:04:04', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'd7ecf3c8-564c-4ed9-b529-9eb29d22239f' | System | 09 Aug 2020 03:02:33 |
| User entered 'None (1)' | System | 09 Aug 2020 03:02:33 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-08T23:04:18', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'd7ecf3c8-564c-4ed9-b529-9eb29d22239f' | System | 09 Aug 2020 03:02:33 |
| User entered 'No (N)' | System | 09 Aug 2020 03:02:33 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-08T23:04:24', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'd7ecf3c8-564c-4ed9-b529-9eb29d22239f' | System | 09 Aug 2020 03:02:33 |
| User entered 'No (N)' | System | 09 Aug 2020 03:02:33 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-08T23:04:28', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'd7ecf3c8-564c-4ed9-b529-9eb29d22239f' | System | 09 Aug 2020 03:02:33 |
| User entered 'None (1)' | System | 09 Aug 2020 03:02:33 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-08T23:04:33', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'd7ecf3c8-564c-4ed9-b529-9eb29d22239f' | System | 09 Aug 2020 03:02:33 |
| User entered '08 Aug 2020 23:04' | System | 09 Aug 2020 03:02:33 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '08 Aug 2020 12:00' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '09 Aug 2020 11:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 6' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| | | |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:02:20

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| | | |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:02:20

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| | | |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| | | |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:02:20

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| | | |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| | | |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| | | |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '09 Aug 2020 12:00' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '10 Aug 2020 11:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 7' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-10T22:33:38', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '7f937b3a-da20-40b8-a0f8-644452d44a28' | System | 11 Aug 2020 02:31:55 |
| User entered 'None (1)' | System | 11 Aug 2020 02:31:55 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-10T22:33:43', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '7f937b3a-da20-40b8-a0f8-644452d44a28' | System | 11 Aug 2020 02:31:55 |
| User entered 'No (N)' | System | 11 Aug 2020 02:31:55 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-10T22:33:46', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '7f937b3a-da20-40b8-a0f8-644452d44a28' | System | 11 Aug 2020 02:31:55 |
| User entered 'No (N)' | System | 11 Aug 2020 02:31:55 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-10T22:33:53', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '7f937b3a-da20-40b8-a0f8-644452d44a28' | System | 11 Aug 2020 02:31:55 |
| User entered 'None (1)' | System | 11 Aug 2020 02:31:55 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-10T22:34:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '7f937b3a-da20-40b8-a0f8-644452d44a28' | System | 11 Aug 2020 02:31:55 |
| User entered '10 Aug 2020 22:34' | System | 11 Aug 2020 02:31:55 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '10 Aug 2020 12:00' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '11 Aug 2020 11:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

HEADACHE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T12:09:14', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'b0efb966-8c86-418b-b583-f5c2b8d4214b' | System | 04 Aug 2020 16:07:54 |
| User entered 'None (0)' | System | 04 Aug 2020 16:07:54 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

FATIGUE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T12:09:17', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'b0efb966-8c86-418b-b583-f5c2b8d4214b' | System | 04 Aug 2020 16:07:54 |
| User entered 'None (0)' | System | 04 Aug 2020 16:07:54 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T12:09:22', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'b0efb966-8c86-418b-b583-f5c2b8d4214b' | System | 04 Aug 2020 16:07:54 |
| User entered 'None (0)' | System | 04 Aug 2020 16:07:54 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T12:09:27', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'b0efb966-8c86-418b-b583-f5c2b8d4214b' | System | 04 Aug 2020 16:07:54 |
| User entered 'None (0)' | System | 04 Aug 2020 16:07:54 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T12:09:31', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'b0efb966-8c86-418b-b583-f5c2b8d4214b' | System | 04 Aug 2020 16:07:54 |
| User entered 'None (0)' | System | 04 Aug 2020 16:07:54 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

CHILLS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T12:09:35', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'b0efb966-8c86-418b-b583-f5c2b8d4214b' | System | 04 Aug 2020 16:07:54 |
| User entered 'None (0)' | System | 04 Aug 2020 16:07:54 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T12:09:40', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'b0efb966-8c86-418b-b583-f5c2b8d4214b' | System | 04 Aug 2020 16:07:54 |
| User entered 'No (N)' | System | 04 Aug 2020 16:07:54 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T12:09:48', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'b0efb966-8c86-418b-b583-f5c2b8d4214b' | System | 04 Aug 2020 16:07:54 |
| User entered '04 Aug 2020 12:09' | System | 04 Aug 2020 16:07:54 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '04 Aug 2020 11:54' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '04 Aug 2020 14:24' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 1, after vaccination (at home)' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

HEADACHE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T22:43:16', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '623e7e74-b3fc-498e-a00f-4ca9c63a5441' | System | 05 Aug 2020 02:42:04 |
| User entered 'None (0)' | System | 05 Aug 2020 02:42:04 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

FATIGUE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T22:43:19', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '623e7e74-b3fc-498e-a00f-4ca9c63a5441' | System | 05 Aug 2020 02:42:04 |
| User entered 'None (0)' | System | 05 Aug 2020 02:42:04 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T22:43:24', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '623e7e74-b3fc-498e-a00f-4ca9c63a5441' | System | 05 Aug 2020 02:42:04 |
| User entered 'None (0)' | System | 05 Aug 2020 02:42:04 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T22:43:27', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '623e7e74-b3fc-498e-a00f-4ca9c63a5441' | System | 05 Aug 2020 02:42:04 |
| User entered 'None (0)' | System | 05 Aug 2020 02:42:04 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T22:43:30', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '623e7e74-b3fc-498e-a00f-4ca9c63a5441' | System | 05 Aug 2020 02:42:04 |
| User entered 'None (0)' | System | 05 Aug 2020 02:42:04 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

CHILLS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T22:43:34', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '623e7e74-b3fc-498e-a00f-4ca9c63a5441' | System | 05 Aug 2020 02:42:04 |
| User entered 'None (0)' | System | 05 Aug 2020 02:42:04 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T22:43:48', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '623e7e74-b3fc-498e-a00f-4ca9c63a5441' | System | 05 Aug 2020 02:42:04 |
| User entered 'No (N)' | System | 05 Aug 2020 02:42:04 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-04T22:43:58', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '623e7e74-b3fc-498e-a00f-4ca9c63a5441' | System | 05 Aug 2020 02:42:04 |
| User entered '04 Aug 2020 22:43' | System | 05 Aug 2020 02:42:04 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '04 Aug 2020 15:19' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '05 Aug 2020 11:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 2' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

HEADACHE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-05T17:23:23', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'e693f0a8-8bd5-40e1-9488-f2aef9b3c790' | System | 05 Aug 2020 21:22:05 |
| User entered 'None (0)' | System | 05 Aug 2020 21:22:05 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

FATIGUE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-05T17:23:27', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'e693f0a8-8bd5-40e1-9488-f2aef9b3c790' | System | 05 Aug 2020 21:22:05 |
| User entered 'None (0)' | System | 05 Aug 2020 21:22:05 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-05T17:23:32', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'e693f0a8-8bd5-40e1-9488-f2aef9b3c790' | System | 05 Aug 2020 21:22:05 |
| User entered 'None (0)' | System | 05 Aug 2020 21:22:05 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-05T17:23:35', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'e693f0a8-8bd5-40e1-9488-f2aef9b3c790' | System | 05 Aug 2020 21:22:05 |
| User entered 'None (0)' | System | 05 Aug 2020 21:22:05 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-05T17:23:39', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'e693f0a8-8bd5-40e1-9488-f2aef9b3c790' | System | 05 Aug 2020 21:22:05 |
| User entered 'None (0)' | System | 05 Aug 2020 21:22:05 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

CHILLS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-05T17:23:42', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'e693f0a8-8bd5-40e1-9488-f2aef9b3c790' | System | 05 Aug 2020 21:22:05 |
| User entered 'None (0)' | System | 05 Aug 2020 21:22:05 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-05T17:23:54', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'e693f0a8-8bd5-40e1-9488-f2aef9b3c790' | System | 05 Aug 2020 21:22:05 |
| User entered 'No (N)' | System | 05 Aug 2020 21:22:05 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-05T17:24:01', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'e693f0a8-8bd5-40e1-9488-f2aef9b3c790' | System | 05 Aug 2020 21:22:05 |
| User entered '05 Aug 2020 17:24' | System | 05 Aug 2020 21:22:05 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '05 Aug 2020 12:00' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '06 Aug 2020 11:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 3' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

HEADACHE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-06T22:01:10', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '2081b7cb-6d91-4506-815e-aca1194ba0f9' | System | 07 Aug 2020 01:59:42 |
| User entered 'None (0)' | System | 07 Aug 2020 01:59:42 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

FATIGUE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-06T22:01:13', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '2081b7cb-6d91-4506-815e-aca1194ba0f9' | System | 07 Aug 2020 01:59:42 |
| User entered 'None (0)' | System | 07 Aug 2020 01:59:42 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-06T22:01:16', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '2081b7cb-6d91-4506-815e-aca1194ba0f9' | System | 07 Aug 2020 01:59:42 |
| User entered 'None (0)' | System | 07 Aug 2020 01:59:42 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-06T22:01:20', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '2081b7cb-6d91-4506-815e-aca1194ba0f9' | System | 07 Aug 2020 01:59:42 |
| User entered 'None (0)' | System | 07 Aug 2020 01:59:42 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-06T22:01:23', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '2081b7cb-6d91-4506-815e-aca1194ba0f9' | System | 07 Aug 2020 01:59:42 |
| User entered 'None (0)' | System | 07 Aug 2020 01:59:42 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

CHILLS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-06T22:01:25', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '2081b7cb-6d91-4506-815e-aca1194ba0f9' | System | 07 Aug 2020 01:59:42 |
| User entered 'None (0)' | System | 07 Aug 2020 01:59:42 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-06T22:01:36', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '2081b7cb-6d91-4506-815e-aca1194ba0f9' | System | 07 Aug 2020 01:59:42 |
| User entered 'No (N)' | System | 07 Aug 2020 01:59:42 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-06T22:01:40', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '2081b7cb-6d91-4506-815e-aca1194ba0f9' | System | 07 Aug 2020 01:59:42 |
| User entered '06 Aug 2020 22:01' | System | 07 Aug 2020 01:59:42 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '06 Aug 2020 12:00' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '07 Aug 2020 11:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 4' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

HEADACHE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-07T22:19:31', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '315b2e3e-6b32-44de-ab84-a0899244a98d' | System | 08 Aug 2020 02:18:12 |
| User entered 'None (0)' | System | 08 Aug 2020 02:18:12 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

FATIGUE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-07T22:19:35', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '315b2e3e-6b32-44de-ab84-a0899244a98d' | System | 08 Aug 2020 02:18:12 |
| User entered 'None (0)' | System | 08 Aug 2020 02:18:12 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-07T22:19:39', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '315b2e3e-6b32-44de-ab84-a0899244a98d' | System | 08 Aug 2020 02:18:12 |
| User entered 'None (0)' | System | 08 Aug 2020 02:18:12 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-07T22:19:44', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '315b2e3e-6b32-44de-ab84-a0899244a98d' | System | 08 Aug 2020 02:18:12 |
| User entered 'None (0)' | System | 08 Aug 2020 02:18:12 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-07T22:19:50', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '315b2e3e-6b32-44de-ab84-a0899244a98d' | System | 08 Aug 2020 02:18:12 |
| User entered 'None (0)' | System | 08 Aug 2020 02:18:12 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

CHILLS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-07T22:19:54', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '315b2e3e-6b32-44de-ab84-a0899244a98d' | System | 08 Aug 2020 02:18:12 |
| User entered 'None (0)' | System | 08 Aug 2020 02:18:12 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-07T22:20:06', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '315b2e3e-6b32-44de-ab84-a0899244a98d' | System | 08 Aug 2020 02:18:12 |
| User entered 'No (N)' | System | 08 Aug 2020 02:18:12 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-07T22:20:13', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '315b2e3e-6b32-44de-ab84-a0899244a98d' | System | 08 Aug 2020 02:18:12 |
| User entered '07 Aug 2020 22:20' | System | 08 Aug 2020 02:18:12 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '07 Aug 2020 12:00' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '08 Aug 2020 11:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 5' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

HEADACHE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-08T23:04:41', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '7e71a67c-cb44-4c65-825c-5bf28039ed21' | System | 09 Aug 2020 03:03:06 |
| User entered 'None (0)' | System | 09 Aug 2020 03:03:06 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

FATIGUE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-08T23:04:46', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '7e71a67c-cb44-4c65-825c-5bf28039ed21' | System | 09 Aug 2020 03:03:06 |
| User entered 'None (0)' | System | 09 Aug 2020 03:03:06 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-08T23:04:49', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '7e71a67c-cb44-4c65-825c-5bf28039ed21' | System | 09 Aug 2020 03:03:06 |
| User entered 'None (0)' | System | 09 Aug 2020 03:03:06 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-08T23:04:52', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '7e71a67c-cb44-4c65-825c-5bf28039ed21' | System | 09 Aug 2020 03:03:06 |
| User entered 'None (0)' | System | 09 Aug 2020 03:03:06 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-08T23:04:54', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '7e71a67c-cb44-4c65-825c-5bf28039ed21' | System | 09 Aug 2020 03:03:06 |
| User entered 'None (0)' | System | 09 Aug 2020 03:03:06 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

CHILLS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-08T23:04:57', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '7e71a67c-cb44-4c65-825c-5bf28039ed21' | System | 09 Aug 2020 03:03:06 |
| User entered 'None (0)' | System | 09 Aug 2020 03:03:06 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-08T23:05:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '7e71a67c-cb44-4c65-825c-5bf28039ed21' | System | 09 Aug 2020 03:03:06 |
| User entered 'No (N)' | System | 09 Aug 2020 03:03:06 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-08T23:05:07', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '7e71a67c-cb44-4c65-825c-5bf28039ed21' | System | 09 Aug 2020 03:03:06 |
| User entered '08 Aug 2020 23:05' | System | 09 Aug 2020 03:03:06 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '08 Aug 2020 12:00' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '09 Aug 2020 11:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 6' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| | | |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| | | |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| | | |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| | | |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| | | |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| | | |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

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) | 25 Feb 2021 21:27:18 |
| | | |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| | | |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '09 Aug 2020 12:00' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '10 Aug 2020 11:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 7' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

HEADACHE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-10T22:34:06', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'bb797755-4e3e-43cf-b19e-bb67c65209b0' | System | 11 Aug 2020 02:32:35 |
| User entered 'None (0)' | System | 11 Aug 2020 02:32:35 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

FATIGUE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-10T22:34:10', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'bb797755-4e3e-43cf-b19e-bb67c65209b0' | System | 11 Aug 2020 02:32:35 |
| User entered 'None (0)' | System | 11 Aug 2020 02:32:35 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-10T22:34:15', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'bb797755-4e3e-43cf-b19e-bb67c65209b0' | System | 11 Aug 2020 02:32:35 |
| User entered 'None (0)' | System | 11 Aug 2020 02:32:35 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-10T22:34:18', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'bb797755-4e3e-43cf-b19e-bb67c65209b0' | System | 11 Aug 2020 02:32:35 |
| User entered 'None (0)' | System | 11 Aug 2020 02:32:35 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-10T22:34:21', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'bb797755-4e3e-43cf-b19e-bb67c65209b0' | System | 11 Aug 2020 02:32:35 |
| User entered 'None (0)' | System | 11 Aug 2020 02:32:35 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

CHILLS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-10T22:34:24', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'bb797755-4e3e-43cf-b19e-bb67c65209b0' | System | 11 Aug 2020 02:32:35 |
| User entered 'None (0)' | System | 11 Aug 2020 02:32:35 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-10T22:34:31', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'bb797755-4e3e-43cf-b19e-bb67c65209b0' | System | 11 Aug 2020 02:32:35 |
| User entered 'No (N)' | System | 11 Aug 2020 02:32:35 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-08-10T22:34:38', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'bb797755-4e3e-43cf-b19e-bb67c65209b0' | System | 11 Aug 2020 02:32:35 |
| User entered '10 Aug 2020 22:34' | System | 11 Aug 2020 02:32:35 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '10 Aug 2020 12:00' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '11 Aug 2020 11:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:07:05 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) | 11 Aug 2020 20:19:45 |

US3832071

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:07:05 |
| User entered '11 Aug 2020' | Alyssa-Kay Peay (b) (4) | 11 Aug 2020 20:19:45 |

US3832071

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:07:05 |
| User entered 'Contact Made (CONTACT MADE)' | Alyssa-Kay Peay (b) (4) (b) (4) | 11 Aug 2020 20:19:45 |

US3832071

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:07:05 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 11 Aug 2020 20:19:45 |

US3832071

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:16:58 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) (b) (4) | 11 Aug 2020 20:19:51 |

US3832071

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'I' | System | 11 Aug 2020 20:19:51 |

US3832071

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:13 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:08:17 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) | 19 Aug 2020 20:04:11 |

US3832071

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:13 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:08:17 |
| User entered '19 Aug 2020' | Alyssa-Kay Peay (b) (4) | 19 Aug 2020 20:04:11 |

US3832071

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:13 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:08:17 |
| User entered 'Contact Made (CONTACT MADE)' | Alyssa-Kay Peay (b) (4) (b) (4) | 19 Aug 2020 20:04:11 |

US3832071

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:13 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:08:17 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 19 Aug 2020 20:04:11 |

US3832071

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Oct 2020 02:00:04 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) | 19 Aug 2020 20:04:33 |

US3832071

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'I' | System | 19 Aug 2020 20:04:33 |

US3832071

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:13 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:09:14 |
| User entered 'Yes (Y)' | Emma Partin (b) (4) | 25 Aug 2020 14:43:34 |

US3832071

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:13 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:09:14 |
| User entered '25 Aug 2020' | Emma Partin (b) (4) | 25 Aug 2020 14:43:34 |

US3832071

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:13 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:09:14 |
| User entered 'Contact Made (CONTACT MADE)' | Emma Partin (b) (4) (b) (4) | 25 Aug 2020 14:43:34 |

US3832071

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:13 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:09:14 |
| User entered empty. | Emma Partin (b) (4) | 25 Aug 2020 14:43:34 |

US3832071

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:13 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:16:48 |
| User entered 'Yes (Y)' | Emma Partin (b) (4) | 25 Aug 2020 14:43:41 |

US3832071

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'I' | System | 25 Aug 2020 14:43:41 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:02:20

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:09:56 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 13:59:56 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:09:56 |
| User entered '1 Sep 2020' | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 13:59:56 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:09:56 |
| User entered 'Clinic (Clinic)' | Alyssa-Kay Peay (b) (4) (b) (4) | 01 Sep 2020 13:59:56 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:02:20

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'VISIT2' | System | 01 Sep 2020 13:59:56 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

[Timepoint](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Alyssa-Kay Peay (b) (4) (b) (4) | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:13:45 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:13:45 |
| User entered '1 Sep 2020' | Alyssa-Kay Peay (b) (4) (b) (4) | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:13:45 |
| User entered '09:29' | Alyssa-Kay Peay (b) (4) (b) (4) | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered '1 Sep 2020 09:29' | System | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:13:45 |
| User entered '97.4' F | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:13:45 |
| User entered 'Oral (Oral)' | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:13:45 |
| User entered empty. | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:13:45 |
| User entered '75' | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'bpm' | System | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:13:45 |
| User entered '17' | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'breaths/min' | System | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:13:45 |
| User entered '131' | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'mmHg' | System | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:13:45 |
| User entered '84' | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:20

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'mmHg' | System | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

[Timepoint](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Alyssa-Kay Peay (b) (4) (b) (4) | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:13:45 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:13:45 |
| User entered '1 Sep 2020' | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:13:45 |
| User entered '10:27' | Alyssa-Kay Peay (b) (4) (b) (4) | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered '1 Sep 2020 10:27' | System | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:13:45 |
| User entered '97.4' F | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:13:45 |
| User entered 'Oral (Oral)' | Alyssa-Kay Peay (b) (4) (b) (4) | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:13:45 |
| User entered empty. | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:13:45 |
| User entered '76' | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'bpm' | System | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:13:45 |
| User entered '16' | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'breaths/min' | System | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:13:45 |
| User entered '145' | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'mmHg' | System | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:13:45 |
| User entered '86' | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:20

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'mmHg' | System | 01 Sep 2020 14:51:18 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:02:20

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:13:59 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) (b) (4) | 01 Sep 2020 14:00:05 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:02:20

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:13:59 |
| User entered '1 Sep 2020' | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:00:05 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:20

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:14:27 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:00:29 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:20

If No, reason not given

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:14:27 |
| User entered empty. | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:00:29 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:20

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) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:14:27 |
| User entered empty. | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:00:29 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:20

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:20

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:14:27 |
| User entered '1 Sep 2020' | Alyssa-Kay Peay (b) (4) (b) (4) | 01 Sep 2020 14:00:29 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:20

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:14:27 |
| User entered '09:57' | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:00:29 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:20

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered '1 Sep 2020 09:57' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:20

Which arm was used to give treatment?

| Audit | User | Time (GMT) |
|------------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:14:27 |
| User entered 'Left Arm (LEFT ARM)' | Alyssa-Kay Peay (b) (4) (b) (4) | 01 Sep 2020 14:00:29 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:20

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:14:27 |
| User entered 'ONCE' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:20

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'INTRAMUSCULAR' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:20

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:16:08 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) (b) (4) | 01 Sep 2020 14:00:38 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:20

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:16:08 |
| User entered '1 Sep 2020' | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:00:38 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:20

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:16:08 |
| User entered '09:45' | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:00:38 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:20

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered '1 Sep 2020 09:45' | System | 01 Sep 2020 14:00:38 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:02:20

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:16:19 |
| User entered '1 Sep 2020' | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:00:55 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:02:20

[Lab Test](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Alyssa-Kay Peay (b) (4) (b) (4) | 01 Sep 2020 14:00:55 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:02:20

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:16:19 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:00:55 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:02:20

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:16:19 |
| User entered '09:41' | Alyssa-Kay Peay (b) (4) | 01 Sep 2020 14:00:55 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:02:20

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered '1 Sep 2020 09:41' | System | 01 Sep 2020 14:00:55 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:02:20

[Lab Test](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Alyssa-Kay Peay (b) (4) (b) (4) | 01 Sep 2020 14:00:55 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:02:20

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Dec 2020 21:27:50 |
| DataPoint Un-verified. | Alyssa-Kay Peay (b) (4) | 10 Nov 2020 22:01:22 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) Alyssa-Kay Peay (b) (4) | 10 Nov 2020 22:01:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:16:19 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) (b) (4) | 01 Sep 2020 14:00:55 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:02:20

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|--------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Dec 2020 21:27:48 |
| DataPoint Un-verified. | Alyssa-Kay Peay (b) (4) | 10 Nov 2020 22:01:22 |
| User entered empty; reason for change Data Entry Error | (b) (4) Alyssa-Kay Peay (b) (4) | 10 Nov 2020 22:01:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:16:19 |
| User entered '09:41' | Alyssa-Kay Peay (b) (4) (b) (4) | 01 Sep 2020 14:00:55 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:02:20

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered empty. | System | 10 Nov 2020 22:01:22 |
| User entered '1 Sep 2020 09:41' | System | 01 Sep 2020 14:00:55 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:16:35 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) (b) (4) | 01 Sep 2020 14:00:58 |

US3832071

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'I' | System | 01 Sep 2020 14:00:58 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 01 Sep 2020 14:00:29 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T10:31:32', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '0e0cb56b-488f-4ee4-b764-63765fcbf1a6' | System | 01 Sep 2020 14:29:04 |
| User entered 'Yes (Y)' | System | 01 Sep 2020 14:29:04 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T10:31:38', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '0e0cb56b-488f-4ee4-b764-63765fcbf1a6' | System | 01 Sep 2020 14:29:04 |
| User entered '97.4' | System | 01 Sep 2020 14:29:04 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T10:31:43', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '0e0cb56b-488f-4ee4-b764-63765fcbf1a6' | System | 01 Sep 2020 14:29:04 |
| User entered 'No (N)' | System | 01 Sep 2020 14:29:04 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T10:31:48', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '0e0cb56b-488f-4ee4-b764-63765fcbf1a6' | System | 01 Sep 2020 14:29:04 |
| User entered '01 Sep 2020 10:31' | System | 01 Sep 2020 14:29:04 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '01 Sep 2020 10:17' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '01 Sep 2020 12:47' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 01 Sep 2020 14:00:29 |
| User entered 'Day 1, after vaccination (at home)' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T21:52:04', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'a34c48e2-1369-4535-825f-0977534959fe' | System | 02 Sep 2020 01:49:54 |
| User entered 'Yes (Y)' | System | 02 Sep 2020 01:49:54 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T21:52:26', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'a34c48e2-1369-4535-825f-0977534959fe' | System | 02 Sep 2020 01:49:54 |
| User entered '97.1' | System | 02 Sep 2020 01:49:54 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T21:52:31', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'a34c48e2-1369-4535-825f-0977534959fe' | System | 02 Sep 2020 01:49:54 |
| User entered 'No (N)' | System | 02 Sep 2020 01:49:54 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T21:52:37', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'a34c48e2-1369-4535-825f-0977534959fe' | System | 02 Sep 2020 01:49:54 |
| User entered '01 Sep 2020 21:52' | System | 02 Sep 2020 01:49:54 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '01 Sep 2020 13:42' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '02 Sep 2020 11:59' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 01 Sep 2020 14:00:29 |
| User entered 'Day 2' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:02:20

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-02T22:17:35', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'a050058c-84c5-4d91-b03a-0edce0b58870' | System | 03 Sep 2020 02:15:10 |
| User entered 'Yes (Y)' | System | 03 Sep 2020 02:15:10 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:02:20

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-02T22:17:44', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'a050058c-84c5-4d91-b03a-0edce0b58870' | System | 03 Sep 2020 02:15:10 |
| User entered '97.0' | System | 03 Sep 2020 02:15:10 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-02T22:17:52', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'a050058c-84c5-4d91-b03a-0edce0b58870' | System | 03 Sep 2020 02:15:10 |
| User entered 'No (N)' | System | 03 Sep 2020 02:15:10 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-02T22:17:56', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'a050058c-84c5-4d91-b03a-0edce0b58870' | System | 03 Sep 2020 02:15:10 |
| User entered '02 Sep 2020 22:17' | System | 03 Sep 2020 02:15:10 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '02 Sep 2020 12:00' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '03 Sep 2020 11:59' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 01 Sep 2020 14:00:29 |
| User entered 'Day 3' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:02:20

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-03T21:40:54', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '83a027a1-c60f-41c5-9a9f-a3a900047438' | System | 04 Sep 2020 01:38:23 |
| User entered 'Yes (Y)' | System | 04 Sep 2020 01:38:23 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:02:20

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-03T21:41:02', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '83a027a1-c60f-41c5-9a9f-a3a900047438' | System | 04 Sep 2020 01:38:23 |
| User entered '97.4' | System | 04 Sep 2020 01:38:23 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-03T21:41:05', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '83a027a1-c60f-41c5-9a9f-a3a900047438' | System | 04 Sep 2020 01:38:23 |
| User entered 'No (N)' | System | 04 Sep 2020 01:38:23 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-03T21:41:11', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '83a027a1-c60f-41c5-9a9f-a3a900047438' | System | 04 Sep 2020 01:38:23 |
| User entered '03 Sep 2020 21:41' | System | 04 Sep 2020 01:38:23 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '03 Sep 2020 12:00' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '04 Sep 2020 11:59' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 01 Sep 2020 14:00:29 |
| User entered 'Day 4' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:02:20

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-04T21:18:55', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'b2846f7d-a828-46cf-b034-f1dba0cc8624' | System | 05 Sep 2020 01:16:23 |
| User entered 'Yes (Y)' | System | 05 Sep 2020 01:16:23 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:02:20

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-04T21:19:03', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'b2846f7d-a828-46cf-b034-f1dba0cc8624' User entered '97.7' | System | 05 Sep 2020 01:16:23 |
| | System | 05 Sep 2020 01:16:23 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-04T21:19:08', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'b2846f7d-a828-46cf-b034-f1dba0cc8624' | System | 05 Sep 2020 01:16:23 |
| User entered 'No (N)' | System | 05 Sep 2020 01:16:23 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-04T21:19:12', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'b2846f7d-a828-46cf-b034-f1dba0cc8624' | System | 05 Sep 2020 01:16:23 |
| User entered '04 Sep 2020 21:19' | System | 05 Sep 2020 01:16:23 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '04 Sep 2020 12:00' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '05 Sep 2020 11:59' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 01 Sep 2020 14:00:29 |
| User entered 'Day 5' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:02:20

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-05T23:23:13', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '89cedd10-1bf3-44d8-a465-86a987a36fe6' | System | 06 Sep 2020 03:20:38 |
| User entered 'Yes (Y)' | System | 06 Sep 2020 03:20:38 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:02:20

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-05T23:23:21', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '89cedd10-1bf3-44d8-a465-86a987a36fe6' | System | 06 Sep 2020 03:20:38 |
| User entered '96.1' | System | 06 Sep 2020 03:20:38 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-05T23:23:24', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '89cedd10-1bf3-44d8-a465-86a987a36fe6' | System | 06 Sep 2020 03:20:38 |
| User entered 'No (N)' | System | 06 Sep 2020 03:20:38 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-05T23:23:29', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '89cedd10-1bf3-44d8-a465-86a987a36fe6' | System | 06 Sep 2020 03:20:38 |
| User entered '05 Sep 2020 23:23' | System | 06 Sep 2020 03:20:38 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '05 Sep 2020 12:00' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '06 Sep 2020 11:59' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 01 Sep 2020 14:00:29 |
| User entered 'Day 6' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:02:20

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-06T23:49:50', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '5762eed0-3606-42e0-8779-6b91dd499126' | System | 07 Sep 2020 03:47:14 |
| User entered 'Yes (Y)' | System | 07 Sep 2020 03:47:14 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:02:20

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-06T23:50:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '5762eed0-3606-42e0-8779-6b91dd499126' | System | 07 Sep 2020 03:47:14 |
| User entered '97.2' | System | 07 Sep 2020 03:47:14 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-06T23:50:03', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '5762eed0-3606-42e0-8779-6b91dd499126' | System | 07 Sep 2020 03:47:14 |
| User entered 'No (N)' | System | 07 Sep 2020 03:47:14 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-06T23:50:08', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '5762eed0-3606-42e0-8779-6b91dd499126' | System | 07 Sep 2020 03:47:14 |
| User entered '06 Sep 2020 23:50' | System | 07 Sep 2020 03:47:14 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '06 Sep 2020 12:00' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '07 Sep 2020 11:59' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 01 Sep 2020 14:00:29 |
| User entered 'Day 7' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:02:20

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-08T08:39:18', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'e0887ebb-ff4c-445a-9e5e-fe07ca62ec77' | System | 08 Sep 2020 12:36:38 |
| User entered 'Yes (Y)' | System | 08 Sep 2020 12:36:38 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:02:20

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-08T08:39:25', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'e0887ebb-ff4c-445a-9e5e-fe07ca62ec77' | System | 08 Sep 2020 12:36:38 |
| User entered '97.1' | System | 08 Sep 2020 12:36:38 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-08T08:39:28', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'e0887ebb-ff4c-445a-9e5e-fe07ca62ec77' | System | 08 Sep 2020 12:36:38 |
| User entered 'No (N)' | System | 08 Sep 2020 12:36:38 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-08T08:39:34', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'e0887ebb-ff4c-445a-9e5e-fe07ca62ec77' | System | 08 Sep 2020 12:36:38 |
| User entered '08 Sep 2020 08:39' | System | 08 Sep 2020 12:36:38 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '07 Sep 2020 12:00' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '08 Sep 2020 11:59' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 01 Sep 2020 14:00:29 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T10:32:17', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '8abe7b3c-2df6-4a2c-ad81-cdf5b42ee778' | System | 01 Sep 2020 14:29:52 |
| User entered 'None (1)' | System | 01 Sep 2020 14:29:52 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T10:32:20', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '8abe7b3c-2df6-4a2c-ad81-cdf5b42ee778' | System | 01 Sep 2020 14:29:52 |
| User entered 'No (N)' | System | 01 Sep 2020 14:29:52 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T10:32:23', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '8abe7b3c-2df6-4a2c-ad81-cdf5b42ee778' | System | 01 Sep 2020 14:29:52 |
| User entered 'No (N)' | System | 01 Sep 2020 14:29:52 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T10:32:31', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '8abe7b3c-2df6-4a2c-ad81-cdf5b42ee778' | System | 01 Sep 2020 14:29:52 |
| User entered 'None (1)' | System | 01 Sep 2020 14:29:52 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T10:32:37', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '8abe7b3c-2df6-4a2c-ad81-cdf5b42ee778' | System | 01 Sep 2020 14:29:52 |
| User entered '01 Sep 2020 10:32' | System | 01 Sep 2020 14:29:52 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '01 Sep 2020 10:17' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '01 Sep 2020 12:47' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 01 Sep 2020 14:00:29 |
| User entered 'Day 1, after vaccination (at home)' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T21:53:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '3eddacbe-b051-481e-a89f-dc32c7e88d21' | System | 02 Sep 2020 01:50:55 |
| User entered 'Does not interfere with activity (2)' | System | 02 Sep 2020 01:50:55 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T21:53:04', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '3eddacbe-b051-481e-a89f-dc32c7e88d21' | System | 02 Sep 2020 01:50:55 |
| User entered 'No (N)' | System | 02 Sep 2020 01:50:55 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T21:53:19', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '3eddacbe-b051-481e-a89f-dc32c7e88d21' | System | 02 Sep 2020 01:50:55 |
| User entered 'No (N)' | System | 02 Sep 2020 01:50:55 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T21:53:25', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '3eddacbe-b051-481e-a89f-dc32c7e88d21' | System | 02 Sep 2020 01:50:55 |
| User entered 'None (1)' | System | 02 Sep 2020 01:50:55 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T21:53:41', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '3eddacbe-b051-481e-a89f-dc32c7e88d21' | System | 02 Sep 2020 01:50:55 |
| User entered '01 Sep 2020 21:53' | System | 02 Sep 2020 01:50:55 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '01 Sep 2020 13:42' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '02 Sep 2020 11:59' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 01 Sep 2020 14:00:29 |
| User entered 'Day 2' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-02T22:18:06', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '2d821de6-3636-45ad-86f9-ae3fc0287451' | System | 03 Sep 2020 02:15:58 |
| User entered 'Does not interfere with activity (2)' | System | 03 Sep 2020 02:15:58 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:02:20

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-02T22:18:18', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '2d821de6-3636-45ad-86f9-ae3fc0287451' | System | 03 Sep 2020 02:15:58 |
| User entered 'No (N)' | System | 03 Sep 2020 02:15:58 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-02T22:18:29', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '2d821de6-3636-45ad-86f9-ae3fc0287451' | System | 03 Sep 2020 02:15:58 |
| User entered 'No (N)' | System | 03 Sep 2020 02:15:58 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-02T22:18:37', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '2d821de6-3636-45ad-86f9-ae3fc0287451' | System | 03 Sep 2020 02:15:58 |
| User entered 'None (1)' | System | 03 Sep 2020 02:15:58 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-02T22:18:43', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '2d821de6-3636-45ad-86f9-ae3fc0287451' | System | 03 Sep 2020 02:15:58 |
| User entered '02 Sep 2020 22:18' | System | 03 Sep 2020 02:15:58 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '02 Sep 2020 12:00' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '03 Sep 2020 11:59' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 01 Sep 2020 14:00:29 |
| User entered 'Day 3' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-03T21:41:29', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '099c3eaf-60a7-4e3e-b5eb-08c58ccf62e9' | System | 04 Sep 2020 01:39:12 |
| User entered 'Does not interfere with activity (2)' | System | 04 Sep 2020 01:39:12 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-03T21:41:32', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '099c3eaf-60a7-4e3e-b5eb-08c58ccf62e9' | System | 04 Sep 2020 01:39:12 |
| User entered 'No (N)' | System | 04 Sep 2020 01:39:12 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-03T21:41:51', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '099c3eaf-60a7-4e3e-b5eb-08c58ccf62e9' | System | 04 Sep 2020 01:39:12 |
| User entered 'No (N)' | System | 04 Sep 2020 01:39:12 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-03T21:41:55', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '099c3eaf-60a7-4e3e-b5eb-08c58ccf62e9' | System | 04 Sep 2020 01:39:12 |
| User entered 'None (1)' | System | 04 Sep 2020 01:39:12 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-03T21:42:01', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '099c3eaf-60a7-4e3e-b5eb-08c58ccf62e9' | System | 04 Sep 2020 01:39:12 |
| User entered '03 Sep 2020 21:42' | System | 04 Sep 2020 01:39:12 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '03 Sep 2020 12:00' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '04 Sep 2020 11:59' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 01 Sep 2020 14:00:29 |
| User entered 'Day 4' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-04T21:19:31', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '3e7132d3-3065-432f-97ee-9790a0c838b2' | System | 05 Sep 2020 01:17:00 |
| User entered 'None (1)' | System | 05 Sep 2020 01:17:00 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-04T21:19:35', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '3e7132d3-3065-432f-97ee-9790a0c838b2' | System | 05 Sep 2020 01:17:00 |
| User entered 'No (N)' | System | 05 Sep 2020 01:17:00 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-04T21:19:39', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '3e7132d3-3065-432f-97ee-9790a0c838b2' | System | 05 Sep 2020 01:17:00 |
| User entered 'No (N)' | System | 05 Sep 2020 01:17:00 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-04T21:19:46', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '3e7132d3-3065-432f-97ee-9790a0c838b2' | System | 05 Sep 2020 01:17:00 |
| User entered 'None (1)' | System | 05 Sep 2020 01:17:00 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-04T21:19:50', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '3e7132d3-3065-432f-97ee-9790a0c838b2' | System | 05 Sep 2020 01:17:00 |
| User entered '04 Sep 2020 21:19' | System | 05 Sep 2020 01:17:00 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '04 Sep 2020 12:00' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '05 Sep 2020 11:59' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 01 Sep 2020 14:00:29 |
| User entered 'Day 5' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-05T23:23:41', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '23d3bf85-c4e0-4f45-846f-43160b950a72' | System | 06 Sep 2020 03:21:05 |
| User entered 'None (1)' | System | 06 Sep 2020 03:21:05 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:02:20

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-05T23:23:47', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '23d3bf85-c4e0-4f45-846f-43160b950a72' | System | 06 Sep 2020 03:21:05 |
| User entered 'No (N)' | System | 06 Sep 2020 03:21:05 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-05T23:23:50', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '23d3bf85-c4e0-4f45-846f-43160b950a72' | System | 06 Sep 2020 03:21:05 |
| User entered 'No (N)' | System | 06 Sep 2020 03:21:05 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-05T23:23:54', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '23d3bf85-c4e0-4f45-846f-43160b950a72' | System | 06 Sep 2020 03:21:05 |
| User entered 'None (1)' | System | 06 Sep 2020 03:21:05 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-05T23:23:58', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '23d3bf85-c4e0-4f45-846f-43160b950a72' | System | 06 Sep 2020 03:21:05 |
| User entered '05 Sep 2020 23:23' | System | 06 Sep 2020 03:21:05 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '05 Sep 2020 12:00' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '06 Sep 2020 11:59' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 01 Sep 2020 14:00:29 |
| User entered 'Day 6' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-06T23:50:23', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'd07bdc88-d20f-4de4-8e14-c654cafad980' | System | 07 Sep 2020 03:47:47 |
| User entered 'None (1)' | System | 07 Sep 2020 03:47:47 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:02:20

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-06T23:50:29', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'd07bdc88-d20f-4de4-8e14-c654cafad980' | System | 07 Sep 2020 03:47:47 |
| User entered 'No (N)' | System | 07 Sep 2020 03:47:47 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-06T23:50:32', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'd07bdc88-d20f-4de4-8e14-c654cafad980' | System | 07 Sep 2020 03:47:47 |
| User entered 'No (N)' | System | 07 Sep 2020 03:47:47 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-06T23:50:36', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'd07bdc88-d20f-4de4-8e14-c654cafad980' | System | 07 Sep 2020 03:47:47 |
| User entered 'None (1)' | System | 07 Sep 2020 03:47:47 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-06T23:50:41', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'd07bdc88-d20f-4de4-8e14-c654cafad980' | System | 07 Sep 2020 03:47:47 |
| User entered '06 Sep 2020 23:50' | System | 07 Sep 2020 03:47:47 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '06 Sep 2020 12:00' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '07 Sep 2020 11:59' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 01 Sep 2020 14:00:29 |
| User entered 'Day 7' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-08T08:39:41', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '109f3c30-10ca-41f6-acb0-2011328d0475' | System | 08 Sep 2020 12:37:05 |
| User entered 'None (1)' | System | 08 Sep 2020 12:37:05 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-08T08:39:45', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '109f3c30-10ca-41f6-acb0-2011328d0475' | System | 08 Sep 2020 12:37:05 |
| User entered 'No (N)' | System | 08 Sep 2020 12:37:05 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-08T08:39:49', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '109f3c30-10ca-41f6-acb0-2011328d0475' | System | 08 Sep 2020 12:37:05 |
| User entered 'No (N)' | System | 08 Sep 2020 12:37:05 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:02:20

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

Please select one response below

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-08T08:39:54', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '109f3c30-10ca-41f6-acb0-2011328d0475' | System | 08 Sep 2020 12:37:05 |
| User entered 'None (1)' | System | 08 Sep 2020 12:37:05 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:02:20

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-08T08:39:58', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '109f3c30-10ca-41f6-acb0-2011328d0475' | System | 08 Sep 2020 12:37:05 |
| User entered '08 Sep 2020 08:39' | System | 08 Sep 2020 12:37:05 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '07 Sep 2020 12:00' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '08 Sep 2020 11:59' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 01 Sep 2020 14:00:29 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

HEADACHE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T10:33:01', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '7a8730a5-7eac-43fe-91d6-3344e21c9cac' | System | 01 Sep 2020 14:30:44 |
| User entered 'None (0)' | System | 01 Sep 2020 14:30:44 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

FATIGUE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T10:33:04', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '7a8730a5-7eac-43fe-91d6-3344e21c9cac' | System | 01 Sep 2020 14:30:44 |
| User entered 'None (0)' | System | 01 Sep 2020 14:30:44 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T10:33:08', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '7a8730a5-7eac-43fe-91d6-3344e21c9cac' | System | 01 Sep 2020 14:30:44 |
| User entered 'None (0)' | System | 01 Sep 2020 14:30:44 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T10:33:12', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '7a8730a5-7eac-43fe-91d6-3344e21c9cac' | System | 01 Sep 2020 14:30:44 |
| User entered 'None (0)' | System | 01 Sep 2020 14:30:44 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T10:33:16', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '7a8730a5-7eac-43fe-91d6-3344e21c9cac' | System | 01 Sep 2020 14:30:44 |
| User entered 'None (0)' | System | 01 Sep 2020 14:30:44 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

CHILLS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T10:33:19', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '7a8730a5-7eac-43fe-91d6-3344e21c9cac' | System | 01 Sep 2020 14:30:44 |
| User entered 'None (0)' | System | 01 Sep 2020 14:30:44 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T10:33:24', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '7a8730a5-7eac-43fe-91d6-3344e21c9cac' | System | 01 Sep 2020 14:30:44 |
| User entered 'No (N)' | System | 01 Sep 2020 14:30:44 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T10:33:29', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '7a8730a5-7eac-43fe-91d6-3344e21c9cac' | System | 01 Sep 2020 14:30:44 |
| User entered '01 Sep 2020 10:33' | System | 01 Sep 2020 14:30:44 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '01 Sep 2020 10:17' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '01 Sep 2020 12:47' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 01 Sep 2020 14:00:29 |
| User entered 'Day 1, after vaccination (at home)' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

HEADACHE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T21:53:47', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '8f771617-78b6-479d-a4e4-09d6d3907100' | System | 02 Sep 2020 01:51:33 |
| User entered 'None (0)' | System | 02 Sep 2020 01:51:33 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

FATIGUE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T21:53:51', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '8f771617-78b6-479d-a4e4-09d6d3907100' | System | 02 Sep 2020 01:51:33 |
| User entered 'None (0)' | System | 02 Sep 2020 01:51:33 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T21:53:55', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '8f771617-78b6-479d-a4e4-09d6d3907100' | System | 02 Sep 2020 01:51:33 |
| User entered 'None (0)' | System | 02 Sep 2020 01:51:33 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T21:53:58', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '8f771617-78b6-479d-a4e4-09d6d3907100' | System | 02 Sep 2020 01:51:33 |
| User entered 'None (0)' | System | 02 Sep 2020 01:51:33 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T21:54:04', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '8f771617-78b6-479d-a4e4-09d6d3907100' | System | 02 Sep 2020 01:51:33 |
| User entered 'None (0)' | System | 02 Sep 2020 01:51:33 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

CHILLS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T21:54:07', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '8f771617-78b6-479d-a4e4-09d6d3907100' | System | 02 Sep 2020 01:51:33 |
| User entered 'None (0)' | System | 02 Sep 2020 01:51:33 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T21:54:13', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '8f771617-78b6-479d-a4e4-09d6d3907100' | System | 02 Sep 2020 01:51:33 |
| User entered 'No (N)' | System | 02 Sep 2020 01:51:33 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-01T21:54:17', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '8f771617-78b6-479d-a4e4-09d6d3907100' | System | 02 Sep 2020 01:51:33 |
| User entered '01 Sep 2020 21:54' | System | 02 Sep 2020 01:51:33 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '01 Sep 2020 13:42' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '02 Sep 2020 11:59' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 01 Sep 2020 14:00:29 |
| User entered 'Day 2' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

HEADACHE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-02T22:18:51', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'b093626c-b4ae-4252-aa69-1389e094635d' | System | 03 Sep 2020 02:16:35 |
| User entered 'None (0)' | System | 03 Sep 2020 02:16:35 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

FATIGUE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-02T22:18:57', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'b093626c-b4ae-4252-aa69-1389e094635d' | System | 03 Sep 2020 02:16:35 |
| User entered 'None (0)' | System | 03 Sep 2020 02:16:35 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-02T22:19:01', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'b093626c-b4ae-4252-aa69-1389e094635d' | System | 03 Sep 2020 02:16:35 |
| User entered 'None (0)' | System | 03 Sep 2020 02:16:35 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-02T22:19:03', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'b093626c-b4ae-4252-aa69-1389e094635d' | System | 03 Sep 2020 02:16:35 |
| User entered 'None (0)' | System | 03 Sep 2020 02:16:35 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-02T22:19:06', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'b093626c-b4ae-4252-aa69-1389e094635d' | System | 03 Sep 2020 02:16:35 |
| User entered 'None (0)' | System | 03 Sep 2020 02:16:35 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

CHILLS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-02T22:19:12', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'b093626c-b4ae-4252-aa69-1389e094635d' | System | 03 Sep 2020 02:16:35 |
| User entered 'None (0)' | System | 03 Sep 2020 02:16:35 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-02T22:19:15', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'b093626c-b4ae-4252-aa69-1389e094635d' | System | 03 Sep 2020 02:16:35 |
| User entered 'No (N)' | System | 03 Sep 2020 02:16:35 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-02T22:19:20', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'b093626c-b4ae-4252-aa69-1389e094635d' | System | 03 Sep 2020 02:16:35 |
| User entered '02 Sep 2020 22:19' | System | 03 Sep 2020 02:16:35 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '02 Sep 2020 12:00' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '03 Sep 2020 11:59' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 01 Sep 2020 14:00:29 |
| User entered 'Day 3' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

HEADACHE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-03T21:42:06', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'f8f3cbe8-5d9a-49c5-8f97-12c08005317c' | System | 04 Sep 2020 01:39:47 |
| User entered 'None (0)' | System | 04 Sep 2020 01:39:47 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

FATIGUE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-03T21:42:10', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'f8f3cbe8-5d9a-49c5-8f97-12c08005317c' | System | 04 Sep 2020 01:39:47 |
| User entered 'None (0)' | System | 04 Sep 2020 01:39:47 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-03T21:42:14', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'f8f3cbe8-5d9a-49c5-8f97-12c08005317c' | System | 04 Sep 2020 01:39:47 |
| User entered 'None (0)' | System | 04 Sep 2020 01:39:47 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-03T21:42:17', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'f8f3cbe8-5d9a-49c5-8f97-12c08005317c' | System | 04 Sep 2020 01:39:47 |
| User entered 'None (0)' | System | 04 Sep 2020 01:39:47 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-03T21:42:20', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'f8f3cbe8-5d9a-49c5-8f97-12c08005317c' | System | 04 Sep 2020 01:39:47 |
| User entered 'None (0)' | System | 04 Sep 2020 01:39:47 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

CHILLS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-03T21:42:23', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'f8f3cbe8-5d9a-49c5-8f97-12c08005317c' | System | 04 Sep 2020 01:39:47 |
| User entered 'None (0)' | System | 04 Sep 2020 01:39:47 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-03T21:42:30', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'f8f3cbe8-5d9a-49c5-8f97-12c08005317c' | System | 04 Sep 2020 01:39:47 |
| User entered 'No (N)' | System | 04 Sep 2020 01:39:47 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-03T21:42:35', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'f8f3cbe8-5d9a-49c5-8f97-12c08005317c' | System | 04 Sep 2020 01:39:47 |
| User entered '03 Sep 2020 21:42' | System | 04 Sep 2020 01:39:47 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '03 Sep 2020 12:00' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '04 Sep 2020 11:59' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 01 Sep 2020 14:00:29 |
| User entered 'Day 4' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

HEADACHE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-04T21:19:58', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '531bdf3e-502d-4e8f-a1a5-c0e9db6b079c' | System | 05 Sep 2020 01:17:37 |
| User entered 'None (0)' | System | 05 Sep 2020 01:17:37 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

FATIGUE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-04T21:20:01', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '531bdf3e-502d-4e8f-a1a5-c0e9db6b079c' | System | 05 Sep 2020 01:17:37 |
| User entered 'None (0)' | System | 05 Sep 2020 01:17:37 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-04T21:20:03', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '531bdf3e-502d-4e8f-a1a5-c0e9db6b079c' | System | 05 Sep 2020 01:17:37 |
| User entered 'None (0)' | System | 05 Sep 2020 01:17:37 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-04T21:20:06', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '531bdf3e-502d-4e8f-a1a5-c0e9db6b079c' | System | 05 Sep 2020 01:17:37 |
| User entered 'None (0)' | System | 05 Sep 2020 01:17:37 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-04T21:20:09', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '531bdf3e-502d-4e8f-a1a5-c0e9db6b079c' | System | 05 Sep 2020 01:17:37 |
| User entered 'None (0)' | System | 05 Sep 2020 01:17:37 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

CHILLS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-04T21:20:12', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '531bdf3e-502d-4e8f-a1a5-c0e9db6b079c' | System | 05 Sep 2020 01:17:37 |
| User entered 'None (0)' | System | 05 Sep 2020 01:17:37 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-04T21:20:19', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '531bdf3e-502d-4e8f-a1a5-c0e9db6b079c' | System | 05 Sep 2020 01:17:37 |
| User entered 'No (N)' | System | 05 Sep 2020 01:17:37 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-04T21:20:26', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '531bdf3e-502d-4e8f-a1a5-c0e9db6b079c' | System | 05 Sep 2020 01:17:37 |
| User entered '04 Sep 2020 21:20' | System | 05 Sep 2020 01:17:37 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '04 Sep 2020 12:00' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '05 Sep 2020 11:59' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 01 Sep 2020 14:00:29 |
| User entered 'Day 5' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

HEADACHE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-05T23:24:04', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '6772abbc-7c6a-45a4-a05d-ead869bbd9fe' | System | 06 Sep 2020 03:21:35 |
| User entered 'None (0)' | System | 06 Sep 2020 03:21:35 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

FATIGUE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-05T23:24:07', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '6772abbc-7c6a-45a4-a05d-ead869bbd9fe' | System | 06 Sep 2020 03:21:35 |
| User entered 'None (0)' | System | 06 Sep 2020 03:21:35 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-05T23:24:09', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '6772abbc-7c6a-45a4-a05d-ead869bbd9fe' | System | 06 Sep 2020 03:21:35 |
| User entered 'None (0)' | System | 06 Sep 2020 03:21:35 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-05T23:24:11', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '6772abbc-7c6a-45a4-a05d-ead869bbd9fe' | System | 06 Sep 2020 03:21:35 |
| User entered 'None (0)' | System | 06 Sep 2020 03:21:35 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-05T23:24:13', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '6772abbc-7c6a-45a4-a05d-ead869bbd9fe' | System | 06 Sep 2020 03:21:35 |
| User entered 'None (0)' | System | 06 Sep 2020 03:21:35 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

CHILLS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-05T23:24:16', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '6772abbc-7c6a-45a4-a05d-ead869bbd9fe' | System | 06 Sep 2020 03:21:35 |
| User entered 'None (0)' | System | 06 Sep 2020 03:21:35 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-05T23:24:20', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '6772abbc-7c6a-45a4-a05d-ead869bbd9fe' | System | 06 Sep 2020 03:21:35 |
| User entered 'No (N)' | System | 06 Sep 2020 03:21:35 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-05T23:24:25', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '6772abbc-7c6a-45a4-a05d-ead869bbd9fe' | System | 06 Sep 2020 03:21:35 |
| User entered '05 Sep 2020 23:24' | System | 06 Sep 2020 03:21:35 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '05 Sep 2020 12:00' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '06 Sep 2020 11:59' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 01 Sep 2020 14:00:29 |
| User entered 'Day 6' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

HEADACHE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-06T23:50:55', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '874d00c3-6269-472a-8a72-0b7dd6ebb187' | System | 07 Sep 2020 03:48:28 |
| User entered 'None (0)' | System | 07 Sep 2020 03:48:28 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

FATIGUE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-06T23:51:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '874d00c3-6269-472a-8a72-0b7dd6ebb187' | System | 07 Sep 2020 03:48:28 |
| User entered 'None (0)' | System | 07 Sep 2020 03:48:28 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-06T23:51:03', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '874d00c3-6269-472a-8a72-0b7dd6ebb187' | System | 07 Sep 2020 03:48:28 |
| User entered 'None (0)' | System | 07 Sep 2020 03:48:28 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-06T23:51:06', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '874d00c3-6269-472a-8a72-0b7dd6ebb187' | System | 07 Sep 2020 03:48:28 |
| User entered 'None (0)' | System | 07 Sep 2020 03:48:28 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-06T23:51:09', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '874d00c3-6269-472a-8a72-0b7dd6ebb187' | System | 07 Sep 2020 03:48:28 |
| User entered 'None (0)' | System | 07 Sep 2020 03:48:28 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

CHILLS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-06T23:51:11', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '874d00c3-6269-472a-8a72-0b7dd6ebb187' | System | 07 Sep 2020 03:48:28 |
| User entered 'None (0)' | System | 07 Sep 2020 03:48:28 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-06T23:51:15', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '874d00c3-6269-472a-8a72-0b7dd6ebb187' | System | 07 Sep 2020 03:48:28 |
| User entered 'No (N)' | System | 07 Sep 2020 03:48:28 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-06T23:51:22', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '874d00c3-6269-472a-8a72-0b7dd6ebb187' | System | 07 Sep 2020 03:48:28 |
| User entered '06 Sep 2020 23:51' | System | 07 Sep 2020 03:48:28 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '06 Sep 2020 12:00' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '07 Sep 2020 11:59' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 01 Sep 2020 14:00:29 |
| User entered 'Day 7' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

HEADACHE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-08T08:40:04', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '8435d9ad-ab5d-4470-a7de-f37e8ac8fa92' | System | 08 Sep 2020 12:37:36 |
| User entered 'None (0)' | System | 08 Sep 2020 12:37:36 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

FATIGUE

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-08T08:40:07', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '8435d9ad-ab5d-4470-a7de-f37e8ac8fa92' | System | 08 Sep 2020 12:37:36 |
| User entered 'None (0)' | System | 08 Sep 2020 12:37:36 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-08T08:40:11', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '8435d9ad-ab5d-4470-a7de-f37e8ac8fa92' | System | 08 Sep 2020 12:37:36 |
| User entered 'None (0)' | System | 08 Sep 2020 12:37:36 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-08T08:40:14', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '8435d9ad-ab5d-4470-a7de-f37e8ac8fa92' | System | 08 Sep 2020 12:37:36 |
| User entered 'None (0)' | System | 08 Sep 2020 12:37:36 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-08T08:40:17', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '8435d9ad-ab5d-4470-a7de-f37e8ac8fa92' | System | 08 Sep 2020 12:37:36 |
| User entered 'None (0)' | System | 08 Sep 2020 12:37:36 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

CHILLS

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-08T08:40:20', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '8435d9ad-ab5d-4470-a7de-f37e8ac8fa92' | System | 08 Sep 2020 12:37:36 |
| User entered 'None (0)' | System | 08 Sep 2020 12:37:36 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-08T08:40:27', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '8435d9ad-ab5d-4470-a7de-f37e8ac8fa92' | System | 08 Sep 2020 12:37:36 |
| User entered 'No (N)' | System | 08 Sep 2020 12:37:36 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-09-08T08:40:33', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '8435d9ad-ab5d-4470-a7de-f37e8ac8fa92' | System | 08 Sep 2020 12:37:36 |
| User entered '08 Sep 2020 08:40' | System | 08 Sep 2020 12:37:36 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '07 Sep 2020 12:00' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:02:20

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| User entered '08 Sep 2020 11:59' | System | 01 Sep 2020 14:00:29 |

US3832071

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:13 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:22:56 |
| User entered 'Yes (Y)' | Emma Partin (b) (4) | 08 Sep 2020 20:49:43 |

US3832071

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:13 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:22:56 |
| User entered '8 Sep 2020' | Emma Partin (b) (4) | 08 Sep 2020 20:49:43 |

US3832071

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:13 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:22:56 |
| User entered 'Contact Made (CONTACT MADE)' | Emma Partin (b) (4) (b) (4) | 08 Sep 2020 20:49:43 |

US3832071

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:13 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:22:56 |
| User entered empty. | Emma Partin (b) (4) (b) (4) | 08 Sep 2020 20:49:43 |

US3832071

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:13 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:25:51 |
| User entered 'Yes (Y)' | Emma Partin (b) (4) | 08 Sep 2020 20:49:48 |

US3832071

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'I' | System | 08 Sep 2020 20:49:48 |

US3832071

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:26:18 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) (b) (4) | 15 Sep 2020 14:46:44 |

US3832071

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:26:18 |
| User entered '15 Sep 2020' | Alyssa-Kay Peay (b) (4) (b) (4) | 15 Sep 2020 14:46:44 |

US3832071

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:26:18 |
| User entered 'Contact Made (CONTACT MADE)' | Alyssa-Kay Peay (b) (4) (b) (4) | 15 Sep 2020 14:46:44 |

US3832071

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:26:18 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 15 Sep 2020 14:46:44 |

US3832071

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:27:08 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) (b) (4) | 15 Sep 2020 14:46:35 |

US3832071

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'I' | System | 15 Sep 2020 14:46:35 |

US3832071

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:32:18 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) | 22 Sep 2020 18:06:33 |

US3832071

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:32:18 |
| User entered '22 Sep 2020' | Ashten Sheriff (b) (4) | 22 Sep 2020 18:06:33 |

US3832071

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:32:18 |
| User entered 'Contact Made (CONTACT MADE)' | Ashten Sheriff (b) (4) (b) (4) | 22 Sep 2020 18:06:33 |

US3832071

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:32:18 |
| User entered empty. | Ashten Sheriff (b) (4) (b) (4) | 22 Sep 2020 18:06:33 |

US3832071

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:32:59 |
| User entered 'Yes (Y)' | Ashten Sheriff (b) (4) (b) (4) | 22 Sep 2020 18:06:41 |

US3832071

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'I' | System | 22 Sep 2020 18:06:41 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:02:20

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:33:35 |
| User entered 'Yes (Y)' | Emma Partin (b) (4) | 29 Sep 2020 15:19:12 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:33:35 |
| User entered '29 Sep 2020' | Emma Partin (b) (4) | 29 Sep 2020 15:19:12 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:33:35 |
| User entered 'Clinic (Clinic)' | Emma Partin (b) (4) (b) (4) | 29 Sep 2020 15:19:12 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:02:20

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'VISIT3' | System | 29 Sep 2020 15:19:12 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:39:49 |
| User entered 'Yes (Y)' | Emma Partin (b) (4) (b) (4) | 29 Sep 2020 15:19:48 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:39:49 |
| User entered '29 Sep 2020' | Emma Partin (b) (4) | 29 Sep 2020 15:19:48 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:39:49 |
| User entered '09:52' | Emma Partin (b) (4) | 29 Sep 2020 15:19:48 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered '29 Sep 2020 09:52' | System | 29 Sep 2020 15:19:48 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:39:49 |
| User entered '97.6' F | Emma Partin (b) (4) | 29 Sep 2020 15:19:48 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:39:49 |
| User entered 'Oral (Oral)' | Emma Partin (b) (4) | 29 Sep 2020 15:19:48 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:39:49 |
| User entered empty. | Emma Partin (b) (4) | 29 Sep 2020 15:19:48 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:39:49 |
| User entered '78' | Emma Partin (b) (4) | 29 Sep 2020 15:19:48 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'bpm' | System | 29 Sep 2020 15:19:48 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:39:49 |
| User entered '14' | Emma Partin (b) (4) | 29 Sep 2020 15:19:48 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'breaths/min' | System | 29 Sep 2020 15:19:48 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:39:49 |
| User entered '130' | Emma Partin (b) (4) | 29 Sep 2020 15:19:48 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'mmHg' | System | 29 Sep 2020 15:19:48 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:39:49 |
| User entered '83' | Emma Partin (b) (4) | 29 Sep 2020 15:19:48 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'mmHg' | System | 29 Sep 2020 15:19:48 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| | | |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| | | |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:02:20

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:40:39 |
| User entered 'Yes (Y)' | Emma Partin (b) (4) (b) (4) | 29 Sep 2020 15:19:59 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:02:20

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:40:39 |
| User entered '29 Sep 2020' | Emma Partin (b) (4) | 29 Sep 2020 15:19:59 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:20

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Oct 2020 16:41:01 |
| User entered 'Yes (Y)' | Emma Partin (b) (4) (b) (4) | 29 Sep 2020 15:20:10 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:20

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:41:01 |
| User entered '29 Sep 2020' | Emma Partin (b) (4) | 29 Sep 2020 15:20:10 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:20

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:41:01 |
| User entered '10:10' | Emma Partin (b) (4) | 29 Sep 2020 15:20:10 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:20

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered '29 Sep 2020 10:10' | System | 29 Sep 2020 15:20:10 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Feb 2021 14:04:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:41:07 |
| User entered 'Yes (Y)' | Emma Partin (b) (4) | 29 Sep 2020 15:20:15 |

US3832071

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'I' | System | 29 Sep 2020 15:20:15 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 64' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-10-07T14:23:29', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'e1f7b986-6bbf-4c0d-9cf3-01753c66e35c' | System | 07 Oct 2020 18:19:49 |
| User entered 'No (N)' | System | 07 Oct 2020 18:19:49 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-10-07T14:23:34', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'e1f7b986-6bbf-4c0d-9cf3-01753c66e35c' | System | 07 Oct 2020 18:19:49 |
| User entered 'No (N)' | System | 07 Oct 2020 18:19:49 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-10-07T14:23:39', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'e1f7b986-6bbf-4c0d-9cf3-01753c66e35c' | System | 07 Oct 2020 18:19:49 |
| User entered '07 Oct 2020 14:23:39' | System | 07 Oct 2020 18:19:49 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered '04 Oct 2020 00:01' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered '08 Oct 2020 23:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 71' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-10-13T09:55:43', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '5da61b99-60c9-4d33-9c3c-1d3314a023a5' | System | 13 Oct 2020 13:55:55 |
| User entered 'No (N)' | System | 13 Oct 2020 13:55:55 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-10-13T09:55:47', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '5da61b99-60c9-4d33-9c3c-1d3314a023a5' | System | 13 Oct 2020 13:55:55 |
| User entered 'No (N)' | System | 13 Oct 2020 13:55:55 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-10-13T09:55:53', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '5da61b99-60c9-4d33-9c3c-1d3314a023a5' | System | 13 Oct 2020 13:55:55 |
| User entered '13 Oct 2020 09:55:53' | System | 13 Oct 2020 13:55:55 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered '11 Oct 2020 00:01' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered '15 Oct 2020 23:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 78' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-10-20T13:13:53', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '9f828c1b-9ae0-4425-b18b-9d5523b341ee' | System | 20 Oct 2020 17:14:04 |
| User entered 'No (N)' | System | 20 Oct 2020 17:14:04 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-10-20T13:13:58', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '9f828c1b-9ae0-4425-b18b-9d5523b341ee' | System | 20 Oct 2020 17:14:04 |
| User entered 'No (N)' | System | 20 Oct 2020 17:14:04 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-10-20T13:14:02', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '9f828c1b-9ae0-4425-b18b-9d5523b341ee' | System | 20 Oct 2020 17:14:04 |
| User entered '20 Oct 2020 13:14:02' | System | 20 Oct 2020 17:14:04 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered '18 Oct 2020 00:01' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered '22 Oct 2020 23:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 92' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-11-03T12:00:24', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'f2eca6bf-923a-48b6-80bb-dc6f6870ce20' | System | 03 Nov 2020 17:00:51 |
| User entered 'No (N)' | System | 03 Nov 2020 17:00:51 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-11-03T12:00:29', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'f2eca6bf-923a-48b6-80bb-dc6f6870ce20' | System | 03 Nov 2020 17:00:51 |
| User entered 'No (N)' | System | 03 Nov 2020 17:00:51 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-11-03T12:00:33', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'f2eca6bf-923a-48b6-80bb-dc6f6870ce20' | System | 03 Nov 2020 17:00:51 |
| User entered '03 Nov 2020 12:00:33' | System | 03 Nov 2020 17:00:51 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered '01 Nov 2020 00:01' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered '05 Nov 2020 23:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 99' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-11-10T14:50:43', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '0c50b4d5-6cef-4770-a215-5d9881982642' | System | 10 Nov 2020 19:50:58 |
| User entered 'No (N)' | System | 10 Nov 2020 19:50:58 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-11-10T14:50:47', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '0c50b4d5-6cef-4770-a215-5d9881982642' | System | 10 Nov 2020 19:50:58 |
| User entered 'No (N)' | System | 10 Nov 2020 19:50:58 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-11-10T14:50:51', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '0c50b4d5-6cef-4770-a215-5d9881982642' | System | 10 Nov 2020 19:50:58 |
| User entered '10 Nov 2020 14:50:51' | System | 10 Nov 2020 19:50:58 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered '08 Nov 2020 00:01' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered '12 Nov 2020 23:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered 'Day 106' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-11-17T11:17:59', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'ffedbb0a-22f4-44c8-89c6-ea6d8bf5909a' | System | 17 Nov 2020 16:18:03 |
| User entered 'No (N)' | System | 17 Nov 2020 16:18:03 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-11-17T11:18:02', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'ffedbb0a-22f4-44c8-89c6-ea6d8bf5909a' | System | 17 Nov 2020 16:18:03 |
| User entered 'No (N)' | System | 17 Nov 2020 16:18:03 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-11-17T11:18:05', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'ffedbb0a-22f4-44c8-89c6-ea6d8bf5909a' | System | 17 Nov 2020 16:18:03 |
| User entered '17 Nov 2020 11:18:05' | System | 17 Nov 2020 16:18:03 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered '15 Nov 2020 00:01' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 21:27:18 |
| Data entry locked. | System | 04 Aug 2020 15:45:45 |
| User entered '19 Nov 2020 23:59' | System | 04 Aug 2020 15:45:45 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '19 Nov 2020 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '23 Nov 2020 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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 (f2ba2e8b25868434)', Time: '2020-11-30T10:32:36', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '363fc59b-4ed5-45d1-8087-28bb88fc4036' | System | 30 Nov 2020 15:32:44 |
| User entered 'No (N)' | System | 30 Nov 2020 15:32:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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 (f2ba2e8b25868434)', Time: '2020-11-30T10:32:39', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '363fc59b-4ed5-45d1-8087-28bb88fc4036' | System | 30 Nov 2020 15:32:44 |
| User entered 'No (N)' | System | 30 Nov 2020 15:32:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-11-30T10:32:41', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '363fc59b-4ed5-45d1-8087-28bb88fc4036' | System | 30 Nov 2020 15:32:44 |
| User entered '30 Nov 2020 10:32:41' | System | 30 Nov 2020 15:32:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '26 Nov 2020 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '30 Nov 2020 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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 (f2ba2e8b25868434)', Time: '2020-12-07T10:31:32', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '7ff48d1d-5ab6-4f4e-a70d-6237d3f9dd4c' | System | 07 Dec 2020 15:31:51 |
| User entered 'No (N)' | System | 07 Dec 2020 15:31:51 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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 (f2ba2e8b25868434)', Time: '2020-12-07T10:31:40', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '7ff48d1d-5ab6-4f4e-a70d-6237d3f9dd4c' | System | 07 Dec 2020 15:31:51 |
| User entered 'No (N)' | System | 07 Dec 2020 15:31:51 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-12-07T10:31:49', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '7ff48d1d-5ab6-4f4e-a70d-6237d3f9dd4c' | System | 07 Dec 2020 15:31:51 |
| User entered '07 Dec 2020 10:31:49' | System | 07 Dec 2020 15:31:51 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '03 Dec 2020 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '07 Dec 2020 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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 (f2ba2e8b25868434)', Time: '2020-12-10T13:09:33', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '60055c1a-7e91-4784-b958-5b532feed8b1' | System | 10 Dec 2020 18:09:43 |
| User entered 'No (N)' | System | 10 Dec 2020 18:09:43 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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 (f2ba2e8b25868434)', Time: '2020-12-10T13:09:36', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '60055c1a-7e91-4784-b958-5b532feed8b1' | System | 10 Dec 2020 18:09:43 |
| User entered 'No (N)' | System | 10 Dec 2020 18:09:43 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-12-10T13:09:39', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '60055c1a-7e91-4784-b958-5b532feed8b1' User entered '10 Dec 2020 13:09:39' | System | 10 Dec 2020 18:09:43 |
| | System | 10 Dec 2020 18:09:43 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '10 Dec 2020 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '14 Dec 2020 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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 (f2ba2e8b25868434)', Time: '2020-12-20T16:18:04', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '97383ae6-13d9-45b4-819f-b8d2d7a7d9f2' | System | 20 Dec 2020 21:18:13 |
| User entered 'No (N)' | System | 20 Dec 2020 21:18:13 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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 (f2ba2e8b25868434)', Time: '2020-12-20T16:18:07', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '97383ae6-13d9-45b4-819f-b8d2d7a7d9f2' | System | 20 Dec 2020 21:18:13 |
| User entered 'No (N)' | System | 20 Dec 2020 21:18:13 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-12-20T16:18:09', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '97383ae6-13d9-45b4-819f-b8d2d7a7d9f2' | System | 20 Dec 2020 21:18:13 |
| User entered '20 Dec 2020 16:18:09' | System | 20 Dec 2020 21:18:13 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '17 Dec 2020 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '21 Dec 2020 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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 (f2ba2e8b25868434)', Time: '2020-12-24T20:22:08', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '80f179a4-a2d8-4795-a513-2df2af696941' | System | 25 Dec 2020 01:22:22 |
| User entered 'No (N)' | System | 25 Dec 2020 01:22:22 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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 (f2ba2e8b25868434)', Time: '2020-12-24T20:22:12', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '80f179a4-a2d8-4795-a513-2df2af696941' | System | 25 Dec 2020 01:22:22 |
| User entered 'No (N)' | System | 25 Dec 2020 01:22:22 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-12-24T20:22:18', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '80f179a4-a2d8-4795-a513-2df2af696941' | System | 25 Dec 2020 01:22:22 |
| User entered '24 Dec 2020 20:22:18' | System | 25 Dec 2020 01:22:22 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '24 Dec 2020 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '28 Dec 2020 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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 (f2ba2e8b25868434)', Time: '2020-12-31T11:26:18', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'adfadf57-9638-4b4f-91fe-1f49d84c786b' | System | 31 Dec 2020 16:26:30 |
| User entered 'No (N)' | System | 31 Dec 2020 16:26:30 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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 (f2ba2e8b25868434)', Time: '2020-12-31T11:26:23', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'adfadf57-9638-4b4f-91fe-1f49d84c786b' | System | 31 Dec 2020 16:26:30 |
| User entered 'No (N)' | System | 31 Dec 2020 16:26:30 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2020-12-31T11:26:26', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'adfadf57-9638-4b4f-91fe-1f49d84c786b' | System | 31 Dec 2020 16:26:30 |
| User entered '31 Dec 2020 11:26:26' | System | 31 Dec 2020 16:26:30 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '31 Dec 2020 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '04 Jan 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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 (f2ba2e8b25868434)', Time: '2021-01-07T22:56:24', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'cf4eb536-a2bf-4a02-93e6-e428343cfa18' | System | 08 Jan 2021 03:56:37 |
| User entered 'No (N)' | System | 08 Jan 2021 03:56:37 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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 (f2ba2e8b25868434)', Time: '2021-01-07T22:56:28', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'cf4eb536-a2bf-4a02-93e6-e428343cfa18' | System | 08 Jan 2021 03:56:37 |
| User entered 'No (N)' | System | 08 Jan 2021 03:56:37 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2021-01-07T22:56:35', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'cf4eb536-a2bf-4a02-93e6-e428343cfa18' | System | 08 Jan 2021 03:56:37 |
| User entered '07 Jan 2021 22:56:35' | System | 08 Jan 2021 03:56:37 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '07 Jan 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '11 Jan 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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 (f2ba2e8b25868434)', Time: '2021-01-16T12:54:24', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '697b4350-4028-4ca4-a7c8-26b47a5309bb' | System | 16 Jan 2021 17:54:34 |
| User entered 'No (N)' | System | 16 Jan 2021 17:54:34 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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 (f2ba2e8b25868434)', Time: '2021-01-16T12:54:27', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '697b4350-4028-4ca4-a7c8-26b47a5309bb' | System | 16 Jan 2021 17:54:34 |
| User entered 'No (N)' | System | 16 Jan 2021 17:54:34 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2021-01-16T12:54:30', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '697b4350-4028-4ca4-a7c8-26b47a5309bb' | System | 16 Jan 2021 17:54:34 |
| User entered '16 Jan 2021 12:54:30' | System | 16 Jan 2021 17:54:34 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '14 Jan 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '18 Jan 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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 (f2ba2e8b25868434)', Time: '2021-01-21T11:15:55', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '4a85fb63-6400-4140-b990-f03ba20e80dc' | System | 21 Jan 2021 16:16:08 |
| User entered 'No (N)' | System | 21 Jan 2021 16:16:08 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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 (f2ba2e8b25868434)', Time: '2021-01-21T11:15:59', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '4a85fb63-6400-4140-b990-f03ba20e80dc' | System | 21 Jan 2021 16:16:08 |
| User entered 'No (N)' | System | 21 Jan 2021 16:16:08 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2021-01-21T11:16:03', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '4a85fb63-6400-4140-b990-f03ba20e80dc' User entered '21 Jan 2021 11:16:03' | System | 21 Jan 2021 16:16:08 |
| | System | 21 Jan 2021 16:16:08 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '21 Jan 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '25 Jan 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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 (f2ba2e8b25868434)', Time: '2021-02-01T19:25:09', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '394e2164-301e-479e-a42f-a00cae9776c4' | System | 02 Feb 2021 00:25:22 |
| User entered 'No (N)' | System | 02 Feb 2021 00:25:22 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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 (f2ba2e8b25868434)', Time: '2021-02-01T19:25:13', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '394e2164-301e-479e-a42f-a00cae9776c4' | System | 02 Feb 2021 00:25:22 |
| User entered 'No (N)' | System | 02 Feb 2021 00:25:22 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2021-02-01T19:25:18', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '394e2164-301e-479e-a42f-a00cae9776c4' | System | 02 Feb 2021 00:25:22 |
| User entered '01 Feb 2021 19:25:18' | System | 02 Feb 2021 00:25:22 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '28 Jan 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '01 Feb 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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 (f2ba2e8b25868434)', Time: '2021-02-05T14:03:45', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '38262376-5e1a-4f6c-b112-a95d39ce63c2' | System | 05 Feb 2021 19:03:56 |
| User entered 'No (N)' | System | 05 Feb 2021 19:03:56 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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 (f2ba2e8b25868434)', Time: '2021-02-05T14:03:48', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '38262376-5e1a-4f6c-b112-a95d39ce63c2' | System | 05 Feb 2021 19:03:56 |
| User entered 'No (N)' | System | 05 Feb 2021 19:03:56 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2021-02-05T14:03:54', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '38262376-5e1a-4f6c-b112-a95d39ce63c2' | System | 05 Feb 2021 19:03:56 |
| User entered '05 Feb 2021 14:03:54' | System | 05 Feb 2021 19:03:56 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '04 Feb 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '08 Feb 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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 (f2ba2e8b25868434)', Time: '2021-02-11T13:15:20', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '0d158e2b-4e20-482f-a986-0b8312012b93' | System | 11 Feb 2021 18:15:55 |
| User entered 'No (N)' | System | 11 Feb 2021 18:15:55 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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 (f2ba2e8b25868434)', Time: '2021-02-11T13:15:22', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '0d158e2b-4e20-482f-a986-0b8312012b93' | System | 11 Feb 2021 18:15:55 |
| User entered 'No (N)' | System | 11 Feb 2021 18:15:55 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2021-02-11T13:15:25', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '0d158e2b-4e20-482f-a986-0b8312012b93' | System | 11 Feb 2021 18:15:55 |
| User entered '11 Feb 2021 13:15:25' | System | 11 Feb 2021 18:15:55 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '11 Feb 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '15 Feb 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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 (f2ba2e8b25868434)', Time: '2021-02-18T14:16:48', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '68e04cc4-0d6e-4b4c-baf6-45bce8e9ad79' | System | 18 Feb 2021 19:16:57 |
| User entered 'No (N)' | System | 18 Feb 2021 19:16:57 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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 (f2ba2e8b25868434)', Time: '2021-02-18T14:16:51', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '68e04cc4-0d6e-4b4c-baf6-45bce8e9ad79' | System | 18 Feb 2021 19:16:57 |
| User entered 'No (N)' | System | 18 Feb 2021 19:16:57 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2021-02-18T14:16:55', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '68e04cc4-0d6e-4b4c-baf6-45bce8e9ad79' | System | 18 Feb 2021 19:16:57 |
| User entered '18 Feb 2021 14:16:55' | System | 18 Feb 2021 19:16:57 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '18 Feb 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '22 Feb 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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 (f2ba2e8b25868434)', Time: '2021-02-26T11:37:31-05:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'd3a3d531-1c91-4bc3-9eea-22651b022bdb' User entered 'No (N)' | System | 26 Feb 2021 16:37:40 |
| | System | 26 Feb 2021 16:37:40 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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 (f2ba2e8b25868434)', Time: '2021-02-26T11:37:34-05:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'd3a3d531-1c91-4bc3-9eea-22651b022bdb' User entered 'No (N)' | System | 26 Feb 2021 16:37:40 |
| | System | 26 Feb 2021 16:37:40 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2021-02-26T11:37:37-05:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'd3a3d531-1c91-4bc3-9eea-22651b022bdb' User entered '26 Feb 2021 11:37:37' | System | 26 Feb 2021 16:37:40 |
| | System | 26 Feb 2021 16:37:40 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '25 Feb 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '01 Mar 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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 (f2ba2e8b25868434)', Time: '2021-03-05T09:57:24-05:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '18875172-ceb8-487a-b91f-63b09c1d486f' | System | 05 Mar 2021 14:57:37 |
| User entered 'No (N)' | System | 05 Mar 2021 14:57:37 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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 (f2ba2e8b25868434)', Time: '2021-03-05T09:57:27-05:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '18875172-ceb8-487a-b91f-63b09c1d486f' | System | 05 Mar 2021 14:57:37 |
| User entered 'No (N)' | System | 05 Mar 2021 14:57:37 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2021-03-05T09:57:32-05:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '18875172-ceb8-487a-b91f-63b09c1d486f' User entered '05 Mar 2021 09:57:32' | System | 05 Mar 2021 14:57:37 |
| | System | 05 Mar 2021 14:57:37 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '04 Mar 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '08 Mar 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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 (f2ba2e8b25868434)', Time: '2021-03-12T16:13:28-05:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '03208305-d63a-482a-82af-0e731d38e8d1' | System | 12 Mar 2021 21:13:42 |
| User entered 'No (N)' | System | 12 Mar 2021 21:13:42 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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 (f2ba2e8b25868434)', Time: '2021-03-12T16:13:31-05:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '03208305-d63a-482a-82af-0e731d38e8d1' | System | 12 Mar 2021 21:13:42 |
| User entered 'No (N)' | System | 12 Mar 2021 21:13:42 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2021-03-12T16:13:37-05:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '03208305-d63a-482a-82af-0e731d38e8d1' User entered '12 Mar 2021 16:13:37' | System | 12 Mar 2021 21:13:42 |
| | System | 12 Mar 2021 21:13:42 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '11 Mar 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '15 Mar 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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 (f2ba2e8b25868434)', Time: '2021-03-19T10:03:36-04:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'ff4c478a-408e-43c8-91d8-b68f617911db' | System | 19 Mar 2021 14:03:46 |
| User entered 'No (N)' | System | 19 Mar 2021 14:03:46 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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 (f2ba2e8b25868434)', Time: '2021-03-19T10:03:39-04:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'ff4c478a-408e-43c8-91d8-b68f617911db' | System | 19 Mar 2021 14:03:46 |
| User entered 'No (N)' | System | 19 Mar 2021 14:03:46 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2021-03-19T10:03:43-04:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'ff4c478a-408e-43c8-91d8-b68f617911db' | System | 19 Mar 2021 14:03:46 |
| User entered '19 Mar 2021 10:03:43' | System | 19 Mar 2021 14:03:46 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '18 Mar 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '22 Mar 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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 (f2ba2e8b25868434)', Time: '2021-03-25T14:58:46-04:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'ceda5910-b6f9-40fc-8a7f-1eaac9417fe8' | System | 25 Mar 2021 18:58:58 |
| User entered 'No (N)' | System | 25 Mar 2021 18:58:58 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Have you been exposed to someone with 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 (f2ba2e8b25868434)', Time: '2021-03-25T14:58:53-04:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'ceda5910-b6f9-40fc-8a7f-1eaac9417fe8' | System | 25 Mar 2021 18:58:58 |
| User entered 'No (N)' | System | 25 Mar 2021 18:58:58 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2021-03-25T14:58:56-04:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'ceda5910-b6f9-40fc-8a7f-1eaac9417fe8' | System | 25 Mar 2021 18:58:58 |
| User entered '25 Mar 2021 14:58:56' | System | 25 Mar 2021 18:58:58 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '25 Mar 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '29 Mar 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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 (f2ba2e8b25868434)', Time: '2021-04-01T12:25:47-04:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'ea94165b-11e2-4c72-9bab-71f83259dd42' | System | 01 Apr 2021 16:28:20 |
| User entered 'No (N)' | System | 01 Apr 2021 16:28:20 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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 (f2ba2e8b25868434)', Time: '2021-04-01T12:25:50-04:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'ea94165b-11e2-4c72-9bab-71f83259dd42' | System | 01 Apr 2021 16:28:20 |
| User entered 'No (N)' | System | 01 Apr 2021 16:28:20 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2021-04-01T12:25:53-04:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'ea94165b-11e2-4c72-9bab-71f83259dd42' | System | 01 Apr 2021 16:28:20 |
| User entered '01 Apr 2021 12:25:53' | System | 01 Apr 2021 16:28:20 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '01 Apr 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '05 Apr 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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 (f2ba2e8b25868434)', Time: '2021-04-09T05:12:37-04:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'e517369c-9ec7-4b5a-b821-8f5215153b5f' User entered 'No (N)' | System | 09 Apr 2021 09:12:52 |
| | System | 09 Apr 2021 09:12:52 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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 (f2ba2e8b25868434)', Time: '2021-04-09T05:12:42-04:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'e517369c-9ec7-4b5a-b821-8f5215153b5f' | System | 09 Apr 2021 09:12:52 |
| User entered 'No (N)' | System | 09 Apr 2021 09:12:52 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2021-04-09T05:12:47-04:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'e517369c-9ec7-4b5a-b821-8f5215153b5f' | System | 09 Apr 2021 09:12:52 |
| User entered '09 Apr 2021 05:12:47' | System | 09 Apr 2021 09:12:52 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '08 Apr 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '12 Apr 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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 (f2ba2e8b25868434)', Time: '2021-04-15T14:39:46-04:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '50b0ac0e-f992-4e9e-aae5-a916e6b36541' User entered 'No (N)' | System | 15 Apr 2021 18:41:46 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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 (f2ba2e8b25868434)', Time: '2021-04-15T14:39:49-04:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '50b0ac0e-f992-4e9e-aae5-a916e6b36541' | System | 15 Apr 2021 18:41:46 |
| User entered 'No (N)' | System | 15 Apr 2021 18:41:46 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2021-04-15T14:39:52-04:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '50b0ac0e-f992-4e9e-aae5-a916e6b36541' User entered '15 Apr 2021 14:39:52' | System | 15 Apr 2021 18:41:46 |
| | System | 15 Apr 2021 18:41:46 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '15 Apr 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '19 Apr 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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 (f2ba2e8b25868434)', Time: '2021-04-23T12:16:56-04:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'ac43cdc0-053f-4f68-81df-718aa58cdced' User entered 'No (N)' | System | 23 Apr 2021 16:17:13 |
| | System | 23 Apr 2021 16:17:13 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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 (f2ba2e8b25868434)', Time: '2021-04-23T12:17:00-04:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'ac43cdc0-053f-4f68-81df-718aa58cdced' User entered 'No (N)' | System | 23 Apr 2021 16:17:13 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2021-04-23T12:17:02-04:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: 'ac43cdc0-053f-4f68-81df-718aa58cdced' User entered '23 Apr 2021 12:17:02' | System | 23 Apr 2021 16:17:13 |
| | System | 23 Apr 2021 16:17:13 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '22 Apr 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '26 Apr 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[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 (f2ba2e8b25868434)', Time: '2021-04-29T10:04:09-04:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '71258b38-b333-4896-9de1-31eb8486ea07' | System | 29 Apr 2021 14:04:20 |
| User entered 'No (N)' | System | 29 Apr 2021 14:04:20 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

Have you been exposed to someone with 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 (f2ba2e8b25868434)', Time: '2021-04-29T10:04:12-04:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '71258b38-b333-4896-9de1-31eb8486ea07' | System | 29 Apr 2021 14:04:20 |
| User entered 'No (N)' | System | 29 Apr 2021 14:04:20 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2021-04-29T10:04:16-04:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '71258b38-b333-4896-9de1-31eb8486ea07' | System | 29 Apr 2021 14:04:20 |
| User entered '29 Apr 2021 10:04:16' | System | 29 Apr 2021 14:04:20 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '29 Apr 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '03 May 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '06 May 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '10 May 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '13 May 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '17 May 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '20 May 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '24 May 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '27 May 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '31 May 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '03 Jun 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '07 Jun 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '10 Jun 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '14 Jun 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '17 Jun 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '21 Jun 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '24 Jun 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '28 Jun 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '01 Jul 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '05 Jul 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '08 Jul 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '12 Jul 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '15 Jul 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '19 Jul 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '22 Jul 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '26 Jul 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '29 Jul 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '02 Aug 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '05 Aug 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '09 Aug 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '12 Aug 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '16 Aug 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '19 Aug 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '23 Aug 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '26 Aug 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '30 Aug 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '02 Sep 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '06 Sep 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '09 Sep 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '13 Sep 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '16 Sep 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '20 Sep 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '23 Sep 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '27 Sep 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '30 Sep 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '04 Oct 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '07 Oct 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '11 Oct 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '14 Oct 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '18 Oct 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '21 Oct 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '25 Oct 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '28 Oct 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '01 Nov 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '04 Nov 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '08 Nov 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '11 Nov 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '15 Nov 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '18 Nov 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '22 Nov 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '25 Nov 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '29 Nov 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '02 Dec 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '06 Dec 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '09 Dec 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '13 Dec 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '16 Dec 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '20 Dec 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '23 Dec 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '27 Dec 2021 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '30 Dec 2021 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '03 Jan 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '06 Jan 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '10 Jan 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '13 Jan 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '17 Jan 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '20 Jan 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '24 Jan 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '27 Jan 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '31 Jan 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '03 Feb 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '07 Feb 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '10 Feb 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '14 Feb 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '17 Feb 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '21 Feb 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '24 Feb 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '28 Feb 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '03 Mar 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '07 Mar 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '10 Mar 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '14 Mar 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '17 Mar 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '21 Mar 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '24 Mar 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '28 Mar 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '31 Mar 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '04 Apr 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '07 Apr 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '11 Apr 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '14 Apr 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '18 Apr 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '21 Apr 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '25 Apr 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '28 Apr 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '02 May 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '05 May 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '09 May 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '12 May 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '16 May 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '19 May 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '23 May 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '26 May 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '30 May 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '02 Jun 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '06 Jun 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '09 Jun 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '13 Jun 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '16 Jun 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '20 Jun 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '23 Jun 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '27 Jun 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '30 Jun 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '04 Jul 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '07 Jul 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '11 Jul 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '14 Jul 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '18 Jul 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '21 Jul 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '25 Jul 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '28 Jul 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '01 Aug 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '04 Aug 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '08 Aug 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '11 Aug 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '15 Aug 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '18 Aug 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '22 Aug 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '25 Aug 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '29 Aug 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '01 Sep 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '05 Sep 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '08 Sep 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '12 Sep 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '15 Sep 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '19 Sep 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '22 Sep 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '26 Sep 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '29 Sep 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '03 Oct 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '06 Oct 2022 00:01' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:20

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 12:24:44 |
| Amendment Manager: User entered '10 Oct 2022 23:59' | System | 19 Nov 2020 12:24:44 |

US3832071

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:02:20

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) | 25 Apr 2021 19:27:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2021-03-05T09:57:45-05:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '4f01f507-c908-4162-97c1-9bcc906341e1' | System | 05 Mar 2021 14:57:53 |
| User entered 'No (N)' | System | 05 Mar 2021 14:57:53 |

US3832071

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:02:20

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 19:27:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2ba2e8b25868434)', Time: '2021-03-05T09:57:50-05:00', User OID: 'PatientReportedOutcome (US3832071)', ODM File OID: '4f01f507-c908-4162-97c1-9bcc906341e1' User entered '05 Mar 2021 09:57:50' | System | 05 Mar 2021 14:57:53 |
| | System | 05 Mar 2021 14:57:53 |

US3832071

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:13 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 13:37:39 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) | 27 Oct 2020 16:17:57 |

US3832071

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:13 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 13:37:39 |
| User entered '27 Oct 2020' | Alyssa-Kay Peay (b) (4) | 27 Oct 2020 16:17:57 |

US3832071

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:13 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 13:37:39 |
| User entered 'Contact Made (CONTACT MADE)' | Alyssa-Kay Peay (b) (4) | 27 Oct 2020 16:17:57 |

US3832071

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:13 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 13:37:39 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 27 Oct 2020 16:17:57 |

US3832071

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:13 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 13:37:43 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) | 27 Oct 2020 16:18:01 |

US3832071

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 13:49:07 |
| User entered 'I' | System | 27 Oct 2020 16:18:01 |

US3832071

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:30:54 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Jan 2021 15:09:12 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) | 03 Dec 2020 16:46:55 |

US3832071

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:30:54 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Jan 2021 15:09:12 |
| User entered '3 Dec 2020' | Alyssa-Kay Peay (b) (4) | 03 Dec 2020 16:46:55 |

US3832071

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:30:54 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Jan 2021 15:09:12 |
| User entered 'Contact Made (CONTACT MADE)' | Alyssa-Kay Peay (b) (4) | 03 Dec 2020 16:46:55 |

US3832071

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:30:54 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:09:12 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 03 Dec 2020 16:46:55 |

US3832071

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:30:54 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Jan 2021 15:09:18 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) | 03 Dec 2020 16:46:59 |

US3832071

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:30:54 |
| User entered 'I' | System | 03 Dec 2020 16:46:59 |

US3832071

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:30:54 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Jan 2021 15:10:11 |
| User entered 'Yes (Y)' | Emma Partin (b) (4) | 30 Dec 2020 16:47:08 |

US3832071

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:30:54 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Jan 2021 15:10:11 |
| User entered '30 Dec 2020' | Emma Partin (b) (4) | 30 Dec 2020 16:47:08 |

US3832071

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:30:54 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Jan 2021 15:10:11 |
| User entered 'Contact Made (CONTACT MADE)' | Emma Partin (b) (4) | 30 Dec 2020 16:47:08 |

US3832071

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:30:54 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:10:11 |
| User entered empty. | Emma Partin (b) (4) (b) (4) | 30 Dec 2020 16:47:08 |

US3832071

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:30:54 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Jan 2021 13:35:24 |
| User entered 'Yes (Y)' | Emma Partin (b) (4) | 30 Dec 2020 16:47:11 |

US3832071

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:30:54 |
| User entered 'I' | System | 30 Dec 2020 16:47:11 |

US3832071

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:30:54 |
| User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 28-Jan-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you. | (b) (4), (b) (6) | 26 Feb 2021 07:17:41 |
| ' (Site from DM). | | |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:13 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 18 Feb 2021 13:13:54 |
| Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 28-Jan-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you. | Rodolfo Barrera (b) (4) (b) (4) | 09 Feb 2021 14:09:10 |
| ' answered with 'Data updated per source.' (Site from DM). | | |
| User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 28-Jan-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you. | (b) (4), (b) (6) | 09 Feb 2021 07:56:09 |
| ' (Site from DM). | | |
| User entered 'Yes (Y)' | Rodolfo Barrera (b) (4) (b) (4) | 27 Jan 2021 15:05:30 |

US3832071

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:30:54 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:13 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Feb 2021 13:13:54 |
| User entered '27 Jan 2021' | Rodolfo Barrera (b) (4) | 27 Jan 2021 15:05:30 |

US3832071

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:30:54 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:13 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Feb 2021 13:13:54 |
| User entered 'Contact Made (CONTACT MADE)' | Rodolfo Barrera (b) (4) | 27 Jan 2021 15:05:30 |

US3832071

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:30:54 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:13 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 18 Feb 2021 13:13:54 |
| User entered empty. | Rodolfo Barrera (b) (4) (b) (4) | 27 Jan 2021 15:05:30 |

US3832071

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:30:54 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:13 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Feb 2021 13:14:37 |
| User entered 'Yes (Y)' | Rodolfo Barrera (b) (4) | 27 Jan 2021 15:05:35 |

US3832071

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:30:54 |
| User entered 'I' | System | 27 Jan 2021 15:05:35 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:02:20

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 18:03:42 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 08 Mar 2021 12:07:01 |
| User entered 'Yes (Y)' | (b) (4) Emma Partin (b) (4) (b) (4) | 03 Mar 2021 16:36:13 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 18:03:42 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 08 Mar 2021 12:07:01 |
| User entered '2 Mar 2021' | (b) (4) Emma Partin (b) (4) (b) (4) | 03 Mar 2021 16:36:13 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 18:03:42 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 08 Mar 2021 12:07:01 |
| User entered 'Clinic (Clinic)' | (b) (4) Emma Partin (b) (4) (b) (4) | 03 Mar 2021 16:36:13 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:02:20

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'VISIT4' | System | 03 Mar 2021 16:36:13 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 18:04:00 |
| User entered 'No (N)' | Danyel Johnson (b) (4) | 31 Mar 2021 12:19:27 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

Date of assessment (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 18:04:00 |
| User entered empty. | Danyel Johnson (b) (4) | 31 Mar 2021 12:19:27 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 18:04:00 |
| User entered empty. | Danyel Johnson (b) (4) | 31 Mar 2021 12:19:27 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered empty. | System | 31 Mar 2021 12:19:27 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 18:04:00 |
| User entered empty. | Danyel Johnson (b) (4) | 31 Mar 2021 12:19:27 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 18:04:00 |
| User entered empty. | Danyel Johnson (b) (4) | 31 Mar 2021 12:19:27 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 18:04:00 |
| User entered empty. | Danyel Johnson (b) (4) | 31 Mar 2021 12:19:27 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 18:04:00 |
| User entered empty. | Danyel Johnson (b) (4) | 31 Mar 2021 12:19:27 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered empty. | System | 31 Mar 2021 12:19:27 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 18:04:00 |
| User entered empty. | Danyel Johnson (b) (4) | 31 Mar 2021 12:19:27 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered empty. | System | 31 Mar 2021 12:19:27 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 18:04:00 |
| User entered empty. | Danyel Johnson (b) (4) | 31 Mar 2021 12:19:27 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered empty. | System | 31 Mar 2021 12:19:27 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 18:04:00 |
| User entered empty. | Danyel Johnson (b) (4) | 31 Mar 2021 12:19:27 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered empty. | System | 31 Mar 2021 12:19:27 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

Height (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| | | |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:20

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| | | |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:02:20

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 18:04:05 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 08 Mar 2021 12:07:01 |
| User entered 'No (N)' | (b) (4) Emma Partin (b) (4) (b) (4) | 03 Mar 2021 16:36:18 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:02:20

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 18:04:05 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 08 Mar 2021 12:07:01 |
| User entered empty. | (b) (4) | |
| | Emma Partin (b) (4) | 03 Mar 2021 16:36:18 |
| | (b) (4) | |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:20

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 18:04:10 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 08 Mar 2021 12:07:01 |
| User entered 'Yes (Y)' | (b) (4) Emma Partin (b) (4) (b) (4) | 03 Mar 2021 16:36:48 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:20

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 18:04:10 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 08 Mar 2021 12:07:01 |
| User entered '2 Mar 2021' | (b) (4) Emma Partin (b) (4) (b) (4) | 03 Mar 2021 16:36:48 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:20

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 18:04:10 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 08 Mar 2021 12:07:01 |
| User entered '10:15' | (b) (4) Emma Partin (b) (4) (b) (4) | 03 Mar 2021 16:36:48 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:20

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered '2 Mar 2021 10:15' | System | 03 Mar 2021 16:36:48 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 18:04:14 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 08 Mar 2021 12:07:01 |
| User entered 'Yes (Y)' | (b) (4) Emma Partin (b) (4) (b) (4) | 03 Mar 2021 16:36:54 |

US3832071

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:01:15 |
| User entered 'I' | System | 03 Mar 2021 16:36:54 |

US3832071

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 29 Apr 2021 02:19:20 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Rodolfo Barrera (b) (4) | 28 Apr 2021 13:02:45 |
| | (b) (4) | |

US3832071

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 29 Apr 2021 02:19:20 |
| | (b) (4) | |
| User entered '1 Apr 2021' | Rodolfo Barrera (b) (4) | 28 Apr 2021 13:02:45 |
| | (b) (4) | |

US3832071

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 29 Apr 2021 02:19:20 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Rodolfo Barrera (b) (4) | 28 Apr 2021 13:02:45 |

US3832071

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 29 Apr 2021 02:19:20 |
| | (b) (4) | |
| User entered empty. | Rodolfo Barrera (b) (4) | 28 Apr 2021 13:02:45 |
| | (b) (4) | |

US3832071

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 29 Apr 2021 02:19:20 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Rodolfo Barrera (b) (4) | 28 Apr 2021 13:02:51 |
| | (b) (4) | |

US3832071

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 28 Apr 2021 13:02:51 |

US3832071

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 29 Apr 2021 02:19:20 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Rodolfo Barrera (b) (4) | 28 Apr 2021 13:03:06 |
| | (b) (4) | |

US3832071

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 29 Apr 2021 02:19:20 |
| | (b) (4) | |
| User entered '27 Apr 2021' | Rodolfo Barrera (b) (4) | 28 Apr 2021 13:03:06 |
| | (b) (4) | |

US3832071

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 29 Apr 2021 02:19:20 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Rodolfo Barrera (b) (4) | 28 Apr 2021 13:03:06 |

US3832071

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:20

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 29 Apr 2021 02:19:20 |
| | (b) (4) | |
| User entered empty. | Rodolfo Barrera (b) (4) | 28 Apr 2021 13:03:06 |
| | (b) (4) | |

US3832071

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 29 Apr 2021 02:19:20 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Rodolfo Barrera (b) (4) | 28 Apr 2021 13:03:11 |
| | (b) (4) | |

US3832071

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:20

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 28 Apr 2021 13:03:11 |

US3832071

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

Form: Visit Date

Generated On: 10 Jun 2021 10:02:20

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:44:22 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Feb 2021 13:14:52 |
| User entered 'Yes (Y)' | Rodolfo Barrera (b) (4) | 09 Feb 2021 14:07:15 |

US3832071

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

Form: Visit Date

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:44:22 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Feb 2021 13:14:52 |
| User entered '28 Jan 2021' | Rodolfo Barrera (b) (4) | 09 Feb 2021 14:07:15 |

US3832071

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

Form: Visit Date

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:44:22 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Feb 2021 13:14:52 |
| User entered 'Clinic (Clinic)' | Rodolfo Barrera (b) (4) | 09 Feb 2021 14:07:15 |

US3832071

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

Form: Visit Date

Generated On: 10 Jun 2021 10:02:20

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:44:22 |
| User entered 'UNBLND_DECIDE' | System | 09 Feb 2021 14:07:15 |

US3832071

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

Form: Unblinding

Generated On: 10 Jun 2021 10:02:20

Date of updated informed consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:44:22 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Feb 2021 13:16:48 |
| User entered '28 Jan 2021' | Rodolfo Barrera (b) (4) | 09 Feb 2021 14:07:50 |

US3832071

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

Form: Unblinding

Generated On: 10 Jun 2021 10:02:20

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:44:22 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| User entered '0' WR# 5295537 | (b) (4) | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 11:21:00 |

US3832071

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

Form: Unblinding

Generated On: 10 Jun 2021 10:02:20

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:44:22 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Feb 2021 13:16:48 |
| User entered 'Yes (Y)' | Rodolfo Barrera (b) (4) | 09 Feb 2021 14:07:50 |

US3832071

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

Form: Unblinding

Generated On: 10 Jun 2021 10:02:20

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:44:22 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| 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 11:21:00 |

US3832071

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

Form: Unblinding

Generated On: 10 Jun 2021 10:02:20

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:44:22 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Feb 2021 13:16:48 |
| User entered '28 Jan 2021' | Rodolfo Barrera (b) (4) | 09 Feb 2021 14:07:50 |

US3832071

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

Form: Unblinding

Generated On: 10 Jun 2021 10:02:20

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:44:22 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Feb 2021 13:16:48 |
| User entered 'mRNA-1273 (mRNA-1273)' | Rodolfo Barrera (b) (4) | 09 Feb 2021 14:07:50 |

US3832071

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

Form: Unblinding

Generated On: 10 Jun 2021 10:02:20

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:44:22 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Feb 2021 13:16:48 |
| User entered 'mRNA-1273 (mRNA-1273)' | Rodolfo Barrera (b) (4) | 09 Feb 2021 14:07:50 |

US3832071

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

Form: Unblinding

Generated On: 10 Jun 2021 10:02:20

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:44:22 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Feb 2021 13:16:48 |
| User entered 'mRNA-1273 (mRNA-1273)' | Rodolfo Barrera (b) (4) | 09 Feb 2021 14:07:50 |

US3832071

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

Form: Unblinding

Generated On: 10 Jun 2021 10:02:20

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:44:22 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Feb 2021 13:16:48 |
| User entered 'No (N)' | Rodolfo Barrera (b) (4) | 09 Feb 2021 14:07:50 |

US3832071

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

Form: Unblinding

Generated On: 10 Jun 2021 10:02:20

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:44:22 |
| User entered empty. | System | 09 Feb 2021 14:07:50 |

US3832071

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

Form: Unblinding

Generated On: 10 Jun 2021 10:02:20

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:44:22 |
| User entered empty. | System | 09 Feb 2021 14:07:50 |

US3832071

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:20

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:44:22 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Feb 2021 13:17:01 |
| User entered 'Yes (Y)' | Rodolfo Barrera (b) (4) | 09 Feb 2021 14:08:20 |

US3832071

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:20

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:44:22 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Feb 2021 13:17:01 |
| User entered '28 Jan 2021' | Rodolfo Barrera (b) (4) | 09 Feb 2021 14:08:20 |

US3832071

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:20

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:44:22 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Feb 2021 13:17:01 |
| User entered '15:49' | Rodolfo Barrera (b) (4) | 09 Feb 2021 14:08:20 |

US3832071

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:20

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:44:22 |
| User entered '28 Jan 2021 15:49' | System | 09 Feb 2021 14:08:20 |

US3832071

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:02:20

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:44:22 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Feb 2021 13:16:37 |
| User entered 'Yes (Y)' | Rodolfo Barrera (b) (4) | 09 Feb 2021 14:08:44 |

US3832071

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:02:20

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:44:22 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Feb 2021 13:16:37 |
| User entered '28 Jan 2021' | Rodolfo Barrera (b) (4) | 09 Feb 2021 14:08:44 |

US3832071

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:02:20

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:44:22 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Feb 2021 13:16:37 |
| User entered '15:53' | Rodolfo Barrera (b) (4) | 09 Feb 2021 14:08:44 |

US3832071

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:02:20

[Collection Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:44:22 |
| User entered '28 Jan 2021 15:53' | System | 09 Feb 2021 14:08:44 |

US3832071

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:02:20

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 06:48:46 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Apr 2021 21:24:52 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| Signature has been broken. | (b) (4) | |
| | Danyel Johnson (b) (4) | 01 Apr 2021 19:27:26 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) | |
| | Danyel Johnson (b) (4) | 01 Apr 2021 19:27:26 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 08 Mar 2021 12:07:01 |
| | (b) (4) | |
| Signature has been broken. | Danyel Johnson (b) (4) | 26 Feb 2021 14:04:32 |
| | (b) (4) | |
| User entered 'No (N)' reason for change: Data Entry Error | Danyel Johnson (b) (4) | 26 Feb 2021 14:04:32 |
| | (b) (4) | |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| | (b) (4) | |
| DataPoint Un-verified. | Danyel Johnson (b) (4) | 01 Feb 2021 16:13:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Danyel Johnson (b) (4) | 01 Feb 2021 16:13:00 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Dec 2020 20:29:07 |
| | | |
| User entered 'No (N)' | Danyel Johnson (b) (4) | 18 Nov 2020 16:31:38 |
| | (b) (4) | |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[AEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:02:30 |
| User entered | System | 02 Apr 2021 13:01:40 |
| 'USA-US100-2021-mRNA-1273-P301000010' | | |
| User entered 'New' | (b) (4), (b) (6) | 02 Apr 2021 13:01:40 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Adverse event](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis perforated, LLT: Ruptured appendix - version MedDRA\\23.0. | Coder Import (b) (4) | 01 Apr 2021 19:30:09 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 01 Apr 2021 19:30:09 |
| Data point term sent to Coder | System | 01 Apr 2021 19:29:19 |
| User entered 'Ruptured appendix' | Danyel Johnson (b) (4) | 01 Apr 2021 19:29:07 |
| | (b) (4) | |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered 'Yes (Y)' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered 'No (N)' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered 'No (N)' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 29 Apr 2021 02:19:20 |
| User closed query 'PV Query: Event onset date should be the date when first signs and symptoms appeared and not when the subject was hospitalized for the event. Since the subject had abdominal pain 5 days before admitting to hospital, therefore please consider updating the event onset date to the date when first signs and symptoms appeared. ' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 20:40:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Apr 2021 22:27:58 |
| Query 'PV Query: Event onset date should be the date when first signs and symptoms appeared and not when the subject was hospitalized for the event. Since the subject had abdominal pain 5 days before admitting to hospital, therefore please consider updating the event onset date to the date when first signs and symptoms appeared. ' answered with 'Updated per review' (Site from Safety). | Danyel Johnson (b) (4) (b) (4) | 23 Apr 2021 17:54:13 |
| DataPoint Un-verified. | Danyel Johnson (b) (4) (b) (4) | 23 Apr 2021 17:51:59 |
| Signature has been broken. | Danyel Johnson (b) (4) (b) (4) | 23 Apr 2021 17:51:59 |
| User entered '21 Mar 2021' reason for change: Data Entry Error | Danyel Johnson (b) (4) (b) (4) | 23 Apr 2021 17:51:59 |
| User opened query 'PV Query: Event onset date should be the date when first signs and symptoms appeared and not when the subject was hospitalized for the event. Since the subject had abdominal pain 5 days before admitting to hospital, therefore please consider updating the event onset date to the date when first signs and symptoms appeared. ' (Site from Safety). | (b) (4), (b) (6) | 23 Apr 2021 16:13:44 |
| User signature succeeded. | Gowdhami Mohan (b) (4) (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered '26 Mar 2021' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered empty. | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered 'No (N)' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered '27 Mar 2021' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered empty. | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Severity](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered 'Grade 4 (Grade 4)' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered 'Yes (Y)' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered '0' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered '0' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered 'I' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

Hospital Admission Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| 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) | 20 Apr 2021 13:21:42 |
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'COVID testing not completed per review of records' (Site from Safety). | Danyel Johnson (b) (4) (b) (4) | 19 Apr 2021 16:37:43 |
| 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) | 16 Apr 2021 08:51:22 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User closed query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety). | (b) (4), (b) (6) | 09 Apr 2021 13:26:19 |
| Query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' answered with 'Post operative care as the appendix did rupture' (Site from Safety). | Danyel Johnson (b) (4) (b) (4) | 08 Apr 2021 20:19:33 |
| User opened query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety). | (b) (4), (b) (6) | 08 Apr 2021 16:27:17 |
| User entered '26 Mar 2021' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|----------------------------------------------------------------------|
| 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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety). User signature succeeded. | (b) (4), (b) (6) (b) (4) | 16 Apr 2021 13:01:47 |
| 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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Records sent ' (Site from Safety). DataPoint Verified. | Gowdhami Mohan (b) (4) (b) (4) Danyel Johnson (b) (4) (b) (4) | 15 Apr 2021 22:12:23 14 Apr 2021 17:34:22 |
| 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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety). User entered '31 Mar 2021' | (b) (4), (b) (6) (b) (4), (b) (6) Danyel Johnson (b) (4) (b) (4) | 12 Apr 2021 18:08:16 08 Apr 2021 16:27:28 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered 'No (N)' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered empty. | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered '0' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered '0' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered '0' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|------------------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered 'Not Related (NOT RELATED)' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|------------------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered 'Not Related (NOT RELATED)' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|------------------------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered '0' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered 'I' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered 'I' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Outcome](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| User entered empty. | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[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) | 16 Apr 2021 13:01:52 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). | (b) (4), (b) (6) | 16 Apr 2021 13:01:50 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 15 Apr 2021 22:12:23 |
| 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) (4), (b) (6) | 15 Apr 2021 16:14:36 |
| 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 'Records received and updated per review' (Site from Safety). | Danyel Johnson (b) (4) (b) (4) | 14 Apr 2021 17:43:28 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Records have been sent ' (Site from Safety). | Danyel Johnson (b) (4) (b) (4) | 14 Apr 2021 17:42:11 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Narrative](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'Not noted ' (Site from Safety). DataPoint Verified. | Danyel Johnson (b) (4) (b) (4) | 14 Apr 2021 17:36:17 |
| | (b) (4), (b) (6) | 12 Apr 2021 18:08:16 |
| 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) | 08 Apr 2021 16:27:00 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). | (b) (4), (b) (6) | 08 Apr 2021 16:26:51 |
| 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) | 08 Apr 2021 16:26:41 |
| User entered 'Subject contacted for Day 239 subject, reports that on 3/26/2021 that she was admitted to the hospital for a ruptured appendix subject states she had surgery on 3/27/2021 for an appendectomy. Subject was discharged 3/31/2021. Subject is unsure of medications. A medical records release has been sent to the subject to receive records.' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:29:07 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 01 Apr 2021 19:29:07 |

US3832071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:20

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 01 Apr 2021 19:29:07 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:02:20

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 06:48:46 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Jan 2021 18:30:10 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) | 06 Aug 2020 19:37:16 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:20

[Name of Medication](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: FORMOTEROL FUMARATE;GLYCOPYRRONIUM BROMIDE, PRODUCTSYNONYM: BEVESPI AEROSPHERE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 06 Aug 2020 19:41:03 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 06 Aug 2020 19:41:03 |
| Data point term sent to Coder | System | 06 Aug 2020 19:39:37 |
| User entered 'Bevespi Aerosphere' | Alyssa-Kay Peay (b) (4) | 06 Aug 2020 19:38:44 |
| | (b) (4) | |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:20

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'No (N)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:38:44 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:20

[Indication](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'COPD - Chronic Obstructive Pulmonary Disease' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:38:44 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:20

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered '2' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:38:44 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:20

[Dose unit](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'puff (PUFF)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:38:44 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:20

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:38:44 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:20

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'twice daily (BID)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:38:44 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:20

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:38:44 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:20

[Route of administration](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:38:44 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:20

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:38:44 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:20

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 12 Aug 2020 12:11:16 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 06 Aug 2020 19:38:44 |
| User entered 'un Apr 2020' | Alyssa-Kay Peay (b) (4) | 06 Aug 2020 19:38:44 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:20

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered '0' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:38:44 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:20

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:38:44 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:20

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:38:44 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:20

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'No (N)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:38:44 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:20

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 06 Aug 2020 19:38:44 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:20

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Aug 2020 19:38:44 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:20

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 06 Aug 2020 19:38:44 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:20

[Name of Medication](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Aug 2020 16:15:18 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Aug 2020 16:15:18 |
| Data point term sent to Coder | System | 06 Aug 2020 19:39:40 |
| User entered 'Ondansetron' | Alyssa-Kay Peay (b) (4) | 06 Aug 2020 19:39:26 |
| | (b) (4) | |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:20

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'No (N)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:39:26 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:20

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Chronic Nausea' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:39:26 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:20

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered '4' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:39:26 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:20

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'mg (mg)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:39:26 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:20

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:39:26 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:20

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'as needed (PRN)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:39:26 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:20

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:39:26 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:20

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Oral (ORAL)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:39:26 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:20

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:39:26 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:20

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 12 Aug 2020 12:11:33 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 06 Aug 2020 19:39:26 |
| User entered 'un UNK 2019' | Alyssa-Kay Peay (b) (4) | 06 Aug 2020 19:39:26 |
| | (b) (4) | |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:20

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered '0' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:39:26 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:20

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:39:26 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:20

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:39:26 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:20

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'No (N)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:39:26 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:20

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Aug 2020 19:39:26 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:20

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Aug 2020 19:39:26 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:20

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Aug 2020 19:39:26 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:02:20

[Name of Medication](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 06 Aug 2020 19:42:05 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 06 Aug 2020 19:42:05 |
| Data point term sent to Coder | System | 06 Aug 2020 19:40:42 |
| User entered 'Vitamin D3' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:40:19 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:02:20

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'No (N)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:40:19 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:02:20

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Low Vitamin D' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:40:19 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:02:20

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered '50000' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:40:19 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:02:20

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'IU (IU)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:40:19 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:02:20

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:40:19 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:02:20

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'every week (QS)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:40:19 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:02:20

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:40:19 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:02:20

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Oral (ORAL)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:40:19 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:02:20

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:40:19 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:02:20

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 12 Aug 2020 12:11:39 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 06 Aug 2020 19:40:19 |
| User entered 'un May 2020' | Alyssa-Kay Peay (b) (4) | 06 Aug 2020 19:40:19 |
| | (b) (4) | |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:02:20

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered '0' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:40:19 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:02:20

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:40:19 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:02:20

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:40:19 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:02:20

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'No (N)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:40:19 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:02:20

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Aug 2020 19:40:19 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:02:20

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Aug 2020 19:40:19 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:02:20

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '803 (803)' | System | 06 Aug 2020 19:40:19 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:20

[Name of Medication](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 10 Aug 2020 17:36:14 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 10 Aug 2020 17:36:14 |
| Data point term sent to Coder | System | 06 Aug 2020 19:41:43 |
| User entered 'Pantoprazole' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:41:05 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:20

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'No (N)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:41:05 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:20

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'GERD - Gastroesophageal Reflux Disease' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:41:05 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:20

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered '4' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:41:05 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:20

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'mg (mg)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:41:05 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:20

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:41:05 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:20

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'once daily (QD)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:41:05 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:20

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:41:05 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:20

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Oral (ORAL)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:41:05 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:20

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:41:05 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:20

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 12 Aug 2020 12:11:43 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 06 Aug 2020 19:41:05 |
| User entered 'un UNK 2017' | Alyssa-Kay Peay (b) (4) | 06 Aug 2020 19:41:05 |
| | (b) (4) | |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:20

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered '0' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:41:05 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:20

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:41:05 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:20

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:41:05 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:20

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'No (N)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:41:05 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:20

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Aug 2020 19:41:05 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:20

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Aug 2020 19:41:05 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:20

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 06 Aug 2020 19:41:05 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:20

[Name of Medication](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 06 Aug 2020 19:44:00 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 06 Aug 2020 19:44:00 |
| Data point term sent to Coder | System | 06 Aug 2020 19:42:46 |
| User entered 'Levothyroxine' | Alyssa-Kay Peay (b) (4) | 06 Aug 2020 19:42:00 |
| | (b) (4) | |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:20

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'No (N)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:42:00 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:20

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'hypothyroidism' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:42:00 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:20

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered '25' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:42:00 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:20

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'ug (ug)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:42:00 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:20

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:42:00 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:20

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'once daily (QD)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:42:00 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:20

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:42:00 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:20

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Oral (ORAL)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:42:00 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:20

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:42:00 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:20

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 12 Aug 2020 12:11:48 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 06 Aug 2020 19:42:00 |
| User entered 'un UNK 2016' | Alyssa-Kay Peay (b) (4) | 06 Aug 2020 19:42:00 |
| | (b) (4) | |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:20

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered '0' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:42:00 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:20

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:42:00 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:20

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:42:00 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:20

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'No (N)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:42:00 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:20

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Aug 2020 19:42:00 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:20

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Aug 2020 19:42:00 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:20

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 06 Aug 2020 19:42:00 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:20

[Name of Medication](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: ALBUTEROL SULFATE - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 21 Sep 2020 18:27:47 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 21 Sep 2020 18:27:47 |
| | (b) (4) | |
| Data point term sent to Coder | System | 21 Sep 2020 18:26:30 |
| Coding entries removed. | Alyssa-Kay Peay (b) (4) | 21 Sep 2020 18:25:42 |
| | (b) (4) | |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: ALBUTEROL SULFATE - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 06 Aug 2020 22:34:07 |
| | (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 Aug 2020 22:34:07 |
| | (b) (4) | |
| Data point term sent to Coder | System | 06 Aug 2020 19:43:48 |
| User entered 'Albuterol Sulfate' | Alyssa-Kay Peay (b) (4) | 06 Aug 2020 19:43:12 |
| | (b) (4) | |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:20

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'No (N)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:43:12 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:20

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Chronic obstructive pulmonary disease' reason for change: Data Entry Error | Alyssa-Kay Peay (b) (4) (b) (4) | 21 Sep 2020 18:25:42 |
| User entered 'COPD - Chronic Obstructive Pulmonary Disorder' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:43:12 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:20

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| User closed query 'per source, 2.5 mg/3ml. DM would like this in mg since it comes in different strengths. please confirm 2.5' (Site from CRA). DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 14:50:01 |
| | (b) (4), (b) (6) | 28 Jan 2021 14:49:52 |
| Query 'per source, 2.5 mg/3ml. DM would like this in mg since it comes in different strengths. please confirm 2.5' answered with 'Confirmed and updated.' (Site from CRA). | Rodolfo Barrera (b) (4) (b) (4) | 27 Jan 2021 21:35:47 |
| User entered '2.5' reason for change: Data Entry Error | Rodolfo Barrera (b) (4) (b) (4) | 27 Jan 2021 21:35:35 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 19 Jan 2021 15:25:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User opened query 'per source, 2.5 mg/3ml. DM would like this in mg since it comes in different strengths. please confirm 2.5' (Site from CRA). | (b) (4), (b) (6) | 19 Jan 2021 15:16:41 |
| User closed query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered as more than one formulation is available for this medication. Please provide the strength in the medication name as the no. of ML has been specified. Update as applicable.' (Site from DM). | (b) (4), (b) (6) | 12 Oct 2020 11:00:46 |
| Query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered as more than one formulation is available for this medication. Please provide the strength in the medication name as the no. of ML has been specified. Update as applicable.' answered with 'corrected' (Site from DM). | Emma Partin (b) (4) (b) (4) | 07 Oct 2020 18:16:27 |
| User opened query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered as more than one formulation is available for this medication. Please provide the strength in the medication name as the no. of ML has been specified. Update as applicable.' (Site from DM). | (b) (4), (b) (6) | 05 Oct 2020 15:27:53 |
| User entered '3' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:43:12 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:20

[Dose unit](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 14:49:54 |
| User closed query 'per source, 2.5 mg/3ml. DM would like this in mg since it comes in different strengths. please confirm mg.' (Site from CRA). | (b) (4), (b) (6) | 28 Jan 2021 14:49:48 |
| Query 'per source, 2.5 mg/3ml. DM would like this in mg since it comes in different strengths. please confirm mg.' answered with 'Confirmed and updated.' (Site from CRA). | Rodolfo Barrera (b) (4) | 27 Jan 2021 21:35:56 |
| User entered 'mg (mg)' reason for change: Data Entry Error | (b) (4) | 27 Jan 2021 21:35:35 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 19 Jan 2021 15:25:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User opened query 'per source, 2.5 mg/3ml. DM would like this in mg since it comes in different strengths. please confirm mg.' (Site from CRA). | (b) (4), (b) (6) | 19 Jan 2021 15:16:58 |
| User entered 'mL (mL)' | Alyssa-Kay Peay (b) (4) | 06 Aug 2020 19:43:12 |
| | (b) (4) | |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:20

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:43:12 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:20

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'as needed (PRN)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:43:12 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:20

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:43:12 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:20

[Route of administration](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:43:12 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:20

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:43:12 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:20

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 12 Aug 2020 12:11:52 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 06 Aug 2020 19:43:12 |
| User entered 'un UNK 2015' | Alyssa-Kay Peay (b) (4) | 06 Aug 2020 19:43:12 |
| | (b) (4) | |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:20

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered '0' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:43:12 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:20

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:43:12 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:20

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:43:12 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:20

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 21 Sep 2020 18:25:42 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 21 Sep 2020 18:25:42 |
| User entered 'No (N)' reason for change: Data Entry Error | Alyssa-Kay Peay (b) (4) (b) (4) | 21 Sep 2020 18:25:42 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 06 Aug 2020 19:43:12 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:43:12 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:20

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Aug 2020 19:43:12 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:20

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Aug 2020 19:43:12 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:20

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Aug 2020 19:43:12 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:20

Name of Medication

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: VENTOLIN [SALBUTAMOL] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 21 Sep 2020 18:25:41 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 21 Sep 2020 18:25:41 |
| | (b) (4) | |
| Data point term sent to Coder | System | 21 Sep 2020 18:24:24 |
| Data point term sent to Coder | System | 21 Sep 2020 18:23:21 |
| Coding entries removed. | Alyssa-Kay Peay (b) (4) | 21 Sep 2020 18:22:35 |
| | (b) (4) | |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: VENTOLIN [SALBUTAMOL] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 10 Aug 2020 11:47:22 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 10 Aug 2020 11:47:22 |
| | (b) (4) | |
| Data point term sent to Coder | System | 06 Aug 2020 19:44:50 |
| User entered 'Ventolin' | Alyssa-Kay Peay (b) (4) | 06 Aug 2020 19:44:40 |
| | (b) (4) | |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:20

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'No (N)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:44:40 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:20

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Chronic obstructive pulmonary disease' reason for change: Data Entry Error | Alyssa-Kay Peay (b) (4) (b) (4) | 21 Sep 2020 18:23:57 |
| User entered 'COPD- Chronic Obstructive Pulmonary Disorder' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:44:40 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:20

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered '90' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:44:40 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:20

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'ug (ug)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:44:40 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:20

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:44:40 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:20

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'as needed (PRN)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:44:40 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:20

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:44:40 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:20

[Route of administration](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User closed query 'Per MM: Please 1) review the route of administration and confirm/update as necessary; if remains oral, then 2) consider re-coding to R03CC-SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS [ADRENERGICS FOR SYSTEMIC USE-RESPIRATORY SYSTEM-DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES] .' (Site from DM). | (b) (4), (b) (6) | 24 Sep 2020 12:04:40 |
| Query 'Per MM: Please 1) review the route of administration and confirm/update as necessary; if remains oral, then 2) consider re-coding to R03CC-SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS [ADRENERGICS FOR SYSTEMIC USE-RESPIRATORY SYSTEM-DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES] .' answered with 'Updated' (Site from DM). | Alyssa-Kay Peay (b) (4) | 21 Sep 2020 18:24:04 |
| | (b) (4) | |
| User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error | Alyssa-Kay Peay (b) (4) | 21 Sep 2020 18:22:35 |
| | (b) (4) | |
| User opened query 'Per MM: Please 1) review the route of administration and confirm/update as necessary; if remains oral, then 2) consider re-coding to R03CC-SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS [ADRENERGICS FOR SYSTEMIC USE-RESPIRATORY SYSTEM-DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES] .' (Site from DM). | (b) (4), (b) (6) | 15 Sep 2020 10:38:19 |
| | | |
| User entered 'Oral (ORAL)' | Alyssa-Kay Peay (b) (4) | 06 Aug 2020 19:44:40 |
| | (b) (4) | |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:20

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:44:40 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:20

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 12 Aug 2020 12:11:56 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 06 Aug 2020 19:44:40 |
| User entered 'un UNK 2015' | Alyssa-Kay Peay (b) (4) | 06 Aug 2020 19:44:40 |
| | (b) (4) | |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:20

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered '0' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:44:40 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:20

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:44:40 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:20

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:44:40 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:20

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'No (N)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:44:40 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:20

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Aug 2020 19:44:40 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:20

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Aug 2020 19:44:40 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:20

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Aug 2020 19:44:40 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:20

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 10 Aug 2020 23:32:20 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 10 Aug 2020 23:32:20 |
| Data point term sent to Coder | System | 06 Aug 2020 19:45:50 |
| User entered 'Trazodone' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:15 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:20

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'No (N)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:15 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:20

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Depression' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:15 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:20

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered '50' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:15 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:20

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'mg (mg)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:15 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:20

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:15 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:20

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'once daily (QD)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:15 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:20

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:15 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:20

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Oral (ORAL)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:15 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:20

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:15 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:20

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 12 Aug 2020 12:12:01 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 06 Aug 2020 19:45:15 |
| User entered 'un UNK 2019' | Alyssa-Kay Peay (b) (4) | 06 Aug 2020 19:45:15 |
| | (b) (4) | |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:20

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered '0' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:15 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:20

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:15 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:20

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:15 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:20

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'No (N)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:15 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:20

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Aug 2020 19:45:15 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:20

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Aug 2020 19:45:15 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:20

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 06 Aug 2020 19:45:15 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:20

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 21 Oct 2020 17:03:38 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 21 Oct 2020 17:03:38 |
| | (b) (4) | |
| Data point term sent to Coder Coding entries removed. | System | 21 Oct 2020 17:02:29 |
| | Alyssa-Kay Peay (b) (4) | 21 Oct 2020 17:02:12 |
| | (b) (4) | |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 07 Aug 2020 17:09:20 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 07 Aug 2020 17:09:20 |
| | (b) (4) | |
| Data point term sent to Coder User entered 'Celecoxib' | System | 06 Aug 2020 19:45:55 |
| | Alyssa-Kay Peay (b) (4) | 06 Aug 2020 19:45:49 |
| | (b) (4) | |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:20

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'No (N)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:49 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:20

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User closed query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 11 Nov 2020 09:06:45 |
| Query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. | Alyssa-Kay Peay (b) (4) (b) (4) | 21 Oct 2020 17:02:22 |
| ' answered with 'updated per query ' (Site from DM). | | |
| User entered 'osteoARTHRITIS' reason for change: Per Query Resolution | Alyssa-Kay Peay (b) (4) (b) (4) | 21 Oct 2020 17:02:12 |
| User opened query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 21 Oct 2020 06:59:13 |
| User entered 'Arthritis' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:49 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:20

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered '200' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:49 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:20

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'mg (mg)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:49 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:20

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:49 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:20

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'twice daily (BID)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:49 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:20

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:49 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:20

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Oral (ORAL)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:49 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:20

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:49 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:20

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 12 Aug 2020 12:12:05 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 06 Aug 2020 19:45:49 |
| User entered 'un UNK 2016' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:49 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:20

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered '0' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:49 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:20

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:49 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:20

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:49 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:20

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'No (N)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:45:49 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:20

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 06 Aug 2020 19:45:49 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:20

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Aug 2020 19:45:49 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:20

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 06 Aug 2020 19:45:49 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:02:20

[Name of Medication](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, VERY POTENT (GROUP IV), PRODUCT: CLOBETASOL PROPIONATE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 07 Aug 2020 17:36:19 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 07 Aug 2020 17:36:19 |
| | (b) (4) | |
| Data point term sent to Coder | System | 06 Aug 2020 19:48:06 |
| User entered 'Clobetasol Propionate' | Alyssa-Kay Peay (b) (4) | 06 Aug 2020 19:47:53 |
| | (b) (4) | |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:02:20

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'No (N)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:47:53 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:02:20

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Eczema' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:47:53 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:02:20

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered '0.05' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:47:53 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:02:20

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Other (OTHER)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:47:53 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:02:20

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'percent %' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:47:53 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:02:20

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'twice daily (BID)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:47:53 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:02:20

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:47:53 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:02:20

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Topical (TOPICAL)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:47:53 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:02:20

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:47:53 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:02:20

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 12 Aug 2020 12:12:10 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 06 Aug 2020 19:47:53 |
| User entered 'un Jul 2020' | Alyssa-Kay Peay (b) (4) | 06 Aug 2020 19:47:53 |
| | (b) (4) | |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:02:20

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered '0' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:47:53 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:02:20

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:47:53 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:02:20

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:47:53 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:02:20

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'No (N)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:47:53 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:02:20

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 06 Aug 2020 19:47:53 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:02:20

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Aug 2020 19:47:53 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:02:20

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 06 Aug 2020 19:47:53 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:20

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| Reviewed for Data Management. | (b) (4), (b) (6) | 12 Aug 2020 12:12:20 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VORTIOXETINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 10 Aug 2020 10:43:09 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 10 Aug 2020 10:43:09 |
| Data point term sent to Coder | System | 06 Aug 2020 19:50:09 |
| User entered 'Vortioxetine' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:49:50 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:20

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'No (N)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:49:50 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:20

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Depression' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:49:50 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:20

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered '20' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:49:50 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:20

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'mg (mg)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:49:50 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:20

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:49:50 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:20

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'once daily (QD)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:49:50 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:20

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:49:50 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:20

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Oral (ORAL)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:49:50 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:20

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:49:50 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:20

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 12 Aug 2020 12:12:26 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 06 Aug 2020 19:49:50 |
| User entered 'un UNK 2019' | Alyssa-Kay Peay (b) (4) | 06 Aug 2020 19:49:50 |
| | (b) (4) | |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:20

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered '0' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:49:50 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:20

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:49:50 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:20

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:49:50 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:20

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'No (N)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:49:50 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:20

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Aug 2020 19:49:50 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:20

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Aug 2020 19:49:50 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:20

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 06 Aug 2020 19:49:50 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:20

[Name of Medication](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: PREGABALIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 17 Aug 2020 08:48:26 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 17 Aug 2020 08:48:26 |
| Data point term sent to Coder | System | 06 Aug 2020 19:51:10 |
| User entered 'Pregabalin' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:50:41 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:20

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'No (N)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:50:41 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:20

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Fibromyalgia' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:50:41 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:20

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered '200' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:50:41 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:20

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'mg (mg)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:50:41 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:20

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:50:41 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:20

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'once daily (QD)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:50:41 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:20

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:50:41 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:20

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Oral (ORAL)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:50:41 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:20

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:50:41 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:20

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 12 Aug 2020 12:12:31 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 06 Aug 2020 19:50:41 |
| User entered 'un UNK 2016' | Alyssa-Kay Peay (b) (4) | 06 Aug 2020 19:50:41 |
| | (b) (4) | |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:20

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered '0' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:50:41 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:20

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'Yes (Y)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:50:41 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:20

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered empty. | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:50:41 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:20

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 15:24:24 |
| User entered 'No (N)' | Alyssa-Kay Peay (b) (4) (b) (4) | 06 Aug 2020 19:50:41 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:20

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Aug 2020 19:50:41 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:20

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Aug 2020 19:50:41 |

US3832071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:20

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 06 Aug 2020 19:50:41 |

US3832071

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:02:20

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 06:48:46 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4) | (b) (4), (b) (6) |
| | (b) (4), (b) (6) | 15 Dec 2020 20:28:11 |
| User entered 'Yes (Y)' reason for change: New Information | Alyssa-Kay Peay (b) (4) | 03 Dec 2020 16:54:16 |
| User entered 'No (N)' | (b) (4) | |
| | Danyel Johnson (b) (4) | 18 Nov 2020 16:31:49 |
| | (b) (4) | |

US3832071

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:02:20

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 13:38:09 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Dec 2020 20:30:46 |
| User entered '1 Dec 2020' | Alyssa-Kay Peay (b) (4) | 03 Dec 2020 16:54:48 |

US3832071

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:02:20

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 13:38:09 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Dec 2020 20:30:46 |
| User entered 'L5 S1 Herniated Disc Repair' | Alyssa-Kay Peay (b) (4) | 03 Dec 2020 16:54:48 |

US3832071

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:02:20

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 13:38:09 |
| User closed query ' Per CDM: L5 S1 HERNIATED DISC REPAIR- indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 17 Mar 2021 08:44:55 |
| Query ' Per CDM: L5 S1 HERNIATED DISC REPAIR- indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you. ' answered with 'Herniated disc is listed in medical history ' (Site from DM). | Danyel Johnson (b) (4) (b) (4) | 12 Mar 2021 16:22:15 |
| User opened query ' Per CDM: L5 S1 HERNIATED DISC REPAIR- indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 12 Mar 2021 12:35:14 |
| User signature succeeded. | Gowdhami Mohan (b) (4) (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Dec 2020 20:30:46 |
| User entered 'Medical History (MH)' | Alyssa-Kay Peay (b) (4) (b) (4) | 03 Dec 2020 16:54:48 |

US3832071

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:02:20

If indication is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 13:38:09 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 21 Feb 2021 17:01:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 15 Dec 2020 20:30:46 |
| User entered empty. | Alyssa-Kay Peay (b) (4) | 03 Dec 2020 16:54:48 |

US3832071

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:02:20

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:06:05 |
| User entered '27 Mar 2021' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:30:07 |

US3832071

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:02:20

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|-----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:06:05 |
| User entered 'Appendectomy' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:30:07 |

US3832071

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:02:20

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:06:05 |
| User entered 'Adverse Event (AE)' | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:30:07 |

US3832071

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:02:20

If indication is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:06:05 |
| User entered empty. | Danyel Johnson (b) (4) (b) (4) | 01 Apr 2021 19:30:07 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:02:54 |
| User entered | System | 02 Apr 2021 13:01:40 |
| 'USA-US100-2021-MRNA-1273-P301000010' | | |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'Yes (Y)' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'No (N)' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'No (N)' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'Yes (Y)' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'No (N)' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'No (N)' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'No (N)' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'Gowdhami' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'Mohan' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered '1655 E. Greenville St' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'Anderson' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'SC' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered '29621' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Apr 2021 16:56:21 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| User entered 'US' | System | 02 Apr 2021 13:03:12 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 26 Apr 2021 16:56:31 |
| User entered '1' | System | 02 Apr 2021 13:03:12 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:02:54 |
| User entered | System | 02 Apr 2021 13:01:40 |
| 'USA-US100-2021-MRNA-1273-P301000010' | | |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'Yes (Y)' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'No (N)' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'No (N)' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'Yes (Y)' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'No (N)' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'No (N)' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'No (N)' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'Gowdhami' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'Mohan' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered '1655 E. Greenville St' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'Anderson' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'SC' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered '29621' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Apr 2021 16:56:21 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| User entered 'US' | System | 02 Apr 2021 13:03:12 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 26 Apr 2021 16:56:31 |
| User entered '1' | System | 02 Apr 2021 13:03:12 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:02:20

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| User entered '02/Apr/2021 09:03' | System | 02 Apr 2021 13:03:12 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:02:20

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Apr 2021 16:56:21 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| User entered '1' | (b) (4), (b) (6) | 02 Apr 2021 13:03:12 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:02:54 |
| User entered | System | 02 Apr 2021 13:01:40 |
| 'USA-US100-2021-MRNA-1273-P301000010' | | |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'Yes (Y)' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'No (N)' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'No (N)' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'Yes (Y)' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'No (N)' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'No (N)' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'No (N)' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'Gowdhami' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'Mohan' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered '1655 E. Greenville St' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'Anderson' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered 'SC' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 13:03:04 |
| User entered '29621' | System | 02 Apr 2021 13:01:40 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Apr 2021 16:56:21 |
| User signature succeeded. | Gowdhami Mohan (b) (4) | 12 Apr 2021 23:03:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 12:48:26 |
| User entered 'US' | System | 02 Apr 2021 13:03:12 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 26 Apr 2021 16:56:31 |
| User entered '1' | System | 02 Apr 2021 13:03:12 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:02:20

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 29 Apr 2021 02:19:20 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 27 Apr 2021 20:45:17 |
| User entered '26/Apr/2021 11:56' | System | 26 Apr 2021 16:56:31 |

US3832071

Folder: SAE USA-US100-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:02:20

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Gowdhami Mohan (b) (4) | 29 Apr 2021 02:19:20 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 27 Apr 2021 20:45:17 |
| User entered 'I' | (b) (4), (b) (6) | 26 Apr 2021 16:56:31 |